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Presidential Documents

Title 3—

The President

Proclamation 8954 of April 1, 2013

World Autism Awareness Day, 2013

By the President of the United States of America

A Proclamation

Today, public health officials estimate that 1 in every 88 children in America is growing up on the autism spectrum. It is a reality that affects millions of families every day, from the classroom to the job market. And while our country has made progress in supporting Americans with autism spectrum disorders (ASDs), we are only beginning to understand the factors behind the challenges they face. On World Autism Awareness Day, we recommit to helping individuals on the autism spectrum reach their full potential.

To achieve that goal, we need a health care system that works for children and adults with ASDs. The Affordable Care Act prevents insurers from denying coverage to children on the autism spectrum, and it ensures new health plans must cover autism screenings at no cost to parents. Beginning in 2014, the Act will make it illegal for insurance companies to discriminate against men and women with preexisting conditions, including ASDs. And looking ahead, my Administration is investing in medical research that can help unlock tomorrow's breakthroughs in autism detection, intervention, and education.

Leveling the playing field for Americans on the autism spectrum also takes commitment in our schools. That is why we are advancing initiatives to help students with ASDs get a good education free from discrimination and undue hardship. And it is why we are making sure that education can lead to meaningful employment by supporting vocational rehabilitation programs and opening higher education to more people on the autism spectrum.

All Americans should have the chance to live full, independent lives and follow their talents wherever they lead. This month, we recognize Americans with ASDs who are walking through doors of opportunity, and we recommit to opening them wider in the years ahead.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim April 2, 2013, as World Autism Awareness Day. I encourage all Americans to learn more about autism and what they can do to support individuals on the autism spectrum and their families.

IN WITNESS WHEREOF, I have hereunto set my hand this first day of April, in the year of our Lord two thousand thirteen, and of the Independence of the United States of America the two hundred and thirty-seventh.

[FR Doc. 2013–08037
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Rules and Regulations

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

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DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

7 CFR Part 272

RIN 0584–AE07

Supplemental Nutrition Assistance Program: Nutrition Education and Obesity Prevention Grant Program

AGENCY: Food and Nutrition Service (FNS), USDA.

ACTION: Interim rule.

SUMMARY: This rule amends Supplemental Nutrition Assistance Program (SNAP) regulations to implement Section 28 of the Food and Nutrition Act (''FNA'' or the ''Act'') of 2008, as added by Section 241 of the Healthy, Hunger-Free Kids (HHFK) Act of 2010, to award grants to States for provision of nutrition education and obesity prevention programs. These programs will provide services for eligible individuals that promote healthy food choices consistent with the current Dietary Guidelines for Americans (DGAs). This rule provides State agencies with requirements for implementing Section 28 including the grant award process and describes the process for allocating the 100 percent Federal grant funding authorized under the Act to carry out nutrition education and obesity prevention services each fiscal year.

DATES: *Effective Date:* This rule will become effective April 5, 2013.

Comment Date: To be considered, comments on this interim rule must be postmarked on or before June 4, 2013.

ADDRESSES: The Food and Nutrition Service invites interested persons to submit comments on this interim rule. Comments may be submitted by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail:* Send comments to Jane Duffield, Branch Chief, State Administration Branch, Program Accountability and Administration Division, Supplemental Nutrition Assistance Program, Food and Nutrition Service, USDA, 3101 Park Center Drive, Alexandria, VA 22302, (703) 605–4385.
- *Web site:* Go to *http://www.fns.usda.gov.* Follow the online instructions for submitting comments through the link at the Supplemental Nutrition Assistance Program Web site.
- *Email:* Send comments to *SNAP-Ed@fns.udsa.gov.* Include Docket ID Number [FNS–2011–0017], Supplemental Nutrition Assistance Program: Nutrition Education and Obesity Prevention Grant Program Interim Rule in the subject line of the message.
- All comments submitted in response to this interim rule will be included in the record and will be made available to the public. Please be advised that the substance of the comments and the identity of the individuals or entities submitting the comments will be subject to public disclosure. FNS will make the comments publicly available on the Internet via *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Jane Duffield, (703) 605–4385, at the above address.

Executive Summary

I. Purpose of the Regulatory Action

The HHFK Act removes the existing nutrition education program under section 11(f) of the Food and Nutrition Act of 2008 (7 U.S.C. 2011 et seq.), commonly known as SNAP Education (SNAP-Ed), and adds in its place Section 28, the nutrition education and obesity prevention grant program. This rule implements the nutrition education and obesity prevention grant program, which FNS will continue to refer to as SNAP-Ed, and seeks to improve its operation and effectiveness to make the program easier for States to administer while meeting the needs of the low-income population.

The implementation of this Program provides a focus on the critical problem of obesity and allows coordinated services to be provided to participants in Federal assistance programs and other low-income persons. This action will broaden collaboration efforts and relationships in order to provide more flexibility to include a wider range of evidence-based intervention strategies.

II. Summary of the Major Provisions of the Regulatory Action in Question

Target Population

The Act defines individuals eligible for SNAP-Ed services as those who receive SNAP or National School Lunch/School Breakfast Program free or reduced price benefits, individuals residing in a community with a significant low-income population, and other low-income individuals as defined by the Secretary. The Agency decided to ease administrative burden on States for SNAP-Ed so defined low-income individuals for the purposes of SNAP-Ed to include those mentioned above and low-income individuals eligible to receive SNAP benefits or other means-tested Federal assistance programs such as Medicaid or Temporary Assistance for Needy Families (TANF), etc. This definition more closely aligns SNAP-Ed with other FNS, Federal, and State-administered benefit programs.

Nutrition Education State Plans

This rule requires States to submit a Nutrition Education State Plan in order to receive a SNAP-Ed grant, essentially the same procedure as before. The Plans must: identify the use of funding for local projects; ensure that interventions are appropriate for the eligible low-income population; and recognize the population's constrained resources and potential eligibility for Federal nutrition assistance. The rule allows States to propose implementing annual or multi-year SNAP-Ed Plans of up to three years.

Use of Funds

The Act permits States to use funds for evidence-based allowable uses identified by the FNS Administrator in consultation with the Director of the Centers for Disease Control and Prevention (CDC). Under this rule, the definitions for *nutrition education and obesity prevention services* and an *evidence-based approach are provided for States to use in their* SNAP-Ed programming. These definitions provide States with greater flexibility to include environmental approaches and policy level work in addition to nutrition education and health promotion. Expanding these approaches has the

added benefit of supporting more comprehensive anti-obesity efforts in addition to providing greater State flexibility in programming.

Under this rule, States are permitted to use funds to deliver nutrition education and obesity prevention activities using one or more of these approaches: individual or group-based nutrition education, health promotion, and intervention strategies; comprehensive, multi-level interventions; and community and public health approaches. To improve program design, States are encouraged to integrate multiple approaches in implementing their activities.

Coordination

The rule encourages coordination of SNAP-Ed activities with public or privately funded health promotion and nutrition improvement strategies and requires that States describe their coordination activities. Since SNAP-Ed funds are capped, States are strongly encouraged to coordinate with other organizations to leverage financial resources to reach low-income individuals through varied approaches.

Funding

This rule provides grants to States through 100 percent Federal funding, requires no State contribution or match, is the only source of Federal SNAP funds for these activities, and provides a two year period of performance. This rule encourages States to seek public and private financial contribution for SNAP-Ed activities to leverage the Federal SNAP investment. The rule describes the allocation process in which States receive funds based on their share of national SNAP-Ed expenditures for Federal Fiscal Year (FFY) 2009 until FFY 2014 when the allocation formula considers State shares of national SNAP participation as well. In FFY 2014, the ratio of expenditures to participation is 90/10 building progressively to a 50/50 ratio of expenditures to SNAP participation by 2018 and thereafter. The funding provisions of this rule stabilize SNAP-Ed funding and reduce State administrative burden since no State contribution is required.

III. Costs and Benefits

	Primary estimate	Year dollar	Discount rate	Period covered
Benefits				
Qualitative: Provisions in Section 28 will result in a reduction of Federal costs and will reduce administrative and financial burden for States, as well as improve the likelihood that low-income persons eligible for SNAP and other federal means-tested programs will make healthy lifestyle choices.				
Costs				
Annualized Monetized ($millions/year)	.....	.....	.....	.....
Transfers				
Annualized Monetized ($millions/year)	−$131 −$132	2013 2013	7% 3%	FFY2013–2017
The first-year cost reduction for the Federal government is estimated at $158 million, with a total cost reduction of $663 million in the first five years. Impacts are already incorporated into the President's budget baseline.				
From the Federal Government to State SNAP Agencies.				

SUPPLEMENTARY INFORMATION:

I. Procedural Matters

Issuance of an Interim Rule and Date of Effectiveness

USDA, under the provisions of the Administrative Procedure Act at 5 U.S.C. 553(b)(B), finds for good cause that use of prior notice and comment procedures for issuing this interim rule is impracticable. Section 28 of the FNA of 2008, as added by Section 241 of Public Law 111–296, the HHFK Act of 2010, Public Law 111–296 enacted on December 13, 2010, requires publication in the **Federal Register** not later than January 1, 2012 of a ''description of the requirements for the receipt of a grant under this section.'' This statutory language demonstrates that Congress expected the Secretary to publish in the **Federal Register** a description of requirements that have maximum legal effect, not proposed requirements, by January 1, 2012 so that State agencies can rely on those requirements in preparing their fiscal year 2013 Nutrition Education State plans. To have maximum legal effect, USDA believes that such requirements must be in the form of an effective rule published in the **Federal Register**, not merely Agency guidance materials. Furthermore, in Section 28 of the Act Congress mandated that the Secretary consult with the Director of the CDC and outside stakeholders and experts prior to identifying allowable uses of the grant funds. Through USDA's diligent efforts to meet this Congressional mandate, the Agency conducted nearly 25 consultative sessions with the CDC and outside stakeholders and experts over a 6 month period. USDA concludes that there was insufficient time to meet this Congressional mandate and issue both a proposed rule and final rule prior to the statutory deadline. As a result, this interim rule is necessary to comply fully with the requirements of Section 28 of the FNA to ensure that State agencies implement its provisions.

For the same reason of impracticability due to the statutory implementation deadline, under the provisions of the Congressional Review Act at 5 U.S.C. 808(2), USDA for good cause is issuing this rule to be effective upon publication. This date is less than the latest of the 60-day delay in effective date prior to, either the submission of a report to Congress, or after publication of the rule in the **Federal Register**, as required under section 801(a)(3)(A) of the Congressional Review Act.

FNS invites public comment on this interim rule. FNS will consider amendments to the rule based on comments submitted during the 60-day comment period. The agency will address comments and affirm or amend the interim rule in a final rule.

II. Background

The purpose of SNAP-Ed is to improve the likelihood that SNAP participants and eligible low-income people will make healthy food choices within a limited budget and choose active lifestyles consistent with the current Dietary Guidelines for Americans (DGAs) and USDA food guidance. SNAP-Ed is designed to coordinate with other Federal, State, and local efforts to provide nutrition education to low-income individuals and families.

State SNAP agencies have the option of providing nutrition education to persons eligible for SNAP as part of their program operations. FNS staff review and approve annual Nutrition Education State Plans submitted by State agencies that chose to participate in SNAP-Ed. These plans outline the States' activities and budget for the following year.

In FFY 1992, FNS approved $661,000 in Federal funds for SNAP-Ed efforts conducted by seven State agencies. The SNAP-Ed program has grown steadily such that by FFY 2010 FNS approved $380 million in Federal funds to provide SNAP-Ed in 52 State agencies.

SNAP-Ed is delivered through State SNAP agencies who subcontract with implementing agencies for conducting local projects. Prior to the HHFK Act, State SNAP agencies seeking Federal reimbursement for State administrative costs submitted a Nutrition Education State Plan, commonly referred to as a ''SNAP-Ed Plan'', for FNS approval. Criteria for evaluating SNAP-Ed Plans included: timeliness, completeness, presence of a needs assessment, goals/objectives, description of projects, consistency with the DGAs and USDA food guidance, evaluation, coordination of efforts, staffing, budget, assurances, and waivers.

Prior to the addition of Section 28 to the FNA, each year FNS provided SNAP-Ed Plan Guidance that assists States with preparation of SNAP-Ed Plans, describes reporting requirements for Plan activities, serves as a reference for SNAP-Ed policy, and provides a timeline for planning and reporting. The Guidance recommended that SNAP-Ed Plans include behaviorally focused, science-based nutrition education interventions, projects, or social marketing campaigns that fall within the scope of SNAP-Ed and are consistent with FNS priorities. The focus of SNAP-Ed has been:

(1) Health promotion to help SNAP eligibles establish healthy eating habits and a physically active lifestyle and

(2) Primary prevention of disease to help SNAP eligibles that have risk factors for diet-related chronic disease prevent or postpone the onset of disease by establishing healthier eating and more physically active lifestyles.

Purpose of the Rule

The HHFK Act removes the existing nutrition education program under section 11(f) of the FNA of 2008 (7 U.S.C. 2011 et seq.), known as SNAP-Ed, and adds in its place Section 28, the nutrition education and obesity prevention grant program. The rule implements the nutrition education and obesity prevention grant program, which FNS will continue to refer to as SNAP-Ed, and seeks to improve its operation and effectiveness to make the program easier for States to administer while meeting the needs of the low-income population.

This rule provides grants to States through 100 percent Federal funding and requires no State contribution or match. Section 28 of the FNA permits State and private financial contribution to SNAP-Ed activities and this rule encourages States to seek these contributions to leverage their Federal SNAP investment.

Implementation of this provision will provide accountability and transparency through SNAP-Ed Plans and ensure that interventions implemented as part of these Plans recognize the constrained resources of the low-income population and are provided at no cost to recipients. It also encourages greater coordination of projects with other public or privately funded health promotion and nutrition improvement strategies.

The implementation of this Program will continue SNAP's commitment to serving low-income populations while focusing on the critical problem of obesity, a major health concern. Implementation of the nutrition education and obesity prevention grant program allows coordinated services to be provided to participants in Federal assistance programs and other low-income persons. This action will broaden coordination and collaboration efforts and relationships in order to provide more flexibility to include a wider range of evidence-based intervention strategies. It will foster a more effective and comprehensive program to address the critical problem of obesity, especially its effects on low-income Americans.

Consultations

Section 28 of the FNA required FNS to consult with the Director of the CDC and a wide range of stakeholders and experts to identify allowable uses of funds and to strengthen the delivery, oversight, and evaluation of nutrition education and obesity prevention services in the development of this rule. These stakeholders and experts included representatives of advocacy groups, academic and research communities, nutrition and health promotion associations, representatives of Federal, State and local governments, and community service providers.

To assist in the formulation of this rule while meeting the requirements of the Act, FNS conducted an aggressive outreach effort to engage its partners, stakeholders, and experts in consultation on all aspects of the provision. FNS conducted nearly 25 consultative sessions over a 6 month period. These sessions included national stakeholder meetings, listening sessions, webinars, meetings and conference calls with State and local staff, Cooperative Extension Service staff/administrators, nutrition network administrators, Indian Tribal Leaders, nutrition practitioners, researchers, and representatives of community-based organizations that serve low-income and minority populations. Additional meetings and planning sessions were conducted with Federal partners such as the CDC Division of Nutrition, Physical Activity, and Obesity and representatives from various USDA agencies. To broaden opportunities for public input, SNAP established an Internet mailbox as a vehicle to receive informal written comments from stakeholders and the public. These efforts resulted in over 150 stakeholder groups and individuals providing comments and suggestions to FNS through meetings, webinars, listening sessions, and email for re-shaping SNAP-Ed as a more robust program with demonstrated impact.

Nutrition Education State Plans

Prior regulation required that SNAP-Ed Plans include information on the number and positions of staff providing services, a description of nutrition education activities, and assurance that activities benefit SNAP participants and others eligible to receive SNAP. The time frames for Plan submission and approval were also stipulated in prior regulation. Under prior law, State agencies received Federal reimbursement for 50 percent of their allowable administrative costs for approved nutrition education activities. States described these activities in their Plans and the methods they would use to provide their State contribution or match to the Federal reimbursement.

Consistent with prior law, Section 28 of the FNA requires State agency submission of a Nutrition Education State Plan in order to receive a grant for the provision of nutrition education and obesity prevention services. FNS will continue to refer to these Plans as SNAP-Ed Plans. Previous SNAP-Ed Plan Guidance required and Section 28 of the Act mandated that SNAP-Ed Plans:

- Identify the use of funding for local projects;
- Ensure that interventions are appropriate for the eligible low-income population; and
- Recognize the population's constrained resources and potential eligibility for Federal nutrition assistance.

The law calls for a two-year transition period, FFYs 2011 and 2012, during which SNAP-Ed Plans remain consistent with requirements in effect prior to passage of the law, with the exception of the new funding procedures proscribed, i.e., no State match required. Section 28 of the Act further requires that Plans conform to Agency standards set through guidance, grant award documents, or regulation.

Prior to this rule, FNS conveyed policy about the operation of SNAP-Ed to States primarily through annual SNAP-Ed Plan Guidance. During the transition period, SNAP-Ed Plan requirements for SNAP-Ed remained relatively static. This allowed States to adjust to the new funding structure called for in the HHFK Act during the two-year transition period.

FNS received input about SNAP-Ed Plan requirements for FFY 2013 and beyond from stakeholders through its numerous consultations, listening sessions, and email responses. Some stakeholders expressed interest in FNS allowing States the flexibility to submit either annual Plans or multi-year Plans that describe SNAP-Ed activities over more than one fiscal year. FNS has permitted multi-year Plans for SNAP-Ed on a limited basis for several years. FNS has determined that States may propose to implement annual or multi-year SNAP-Ed Plans that cover a timeframe of up to three years.

SNAP-Ed Plans must be submitted by August 15th for FNS approval to receive a grant for provision of nutrition education and obesity prevention services. Approved Plans become effective for the following FFY (October 1st—September 30th). The SNAP-Ed Plans must address the requirements specified by law and meet standards established in this rule, SNAP-Ed Plan Guidance, and other FNS policy. The SNAP-Ed Annual Report that examines project activities and budget for the prior year must be submitted by November 30th of each year.

Target Population

Section 28 of the Act defines individuals eligible for SNAP-Ed services as those who receive SNAP or National School Lunch/School Breakfast Program free or reduced price benefits, individuals residing in a community with a significant low-income population, and other low-income individuals as defined by the Secretary. Under Section 28, State agencies may deliver services either directly to eligible individuals or through agreements with other State or local agencies or community organizations.

Current SNAP-Ed guidance places a priority on nutrition education for SNAP participants and persons eligible to receive SNAP. States can also use SNAP-Ed funds to reach persons in locations where at least half of the population has gross incomes equal to or less than 185 percent of the poverty threshold. For example, SNAP funds may be used to serve persons residing, attending school, or in some circumstances shopping for food in low-income areas.

Through consultations, some stakeholders recommended that FNS expand the current definition of SNAP-Ed eligible. Considering its goal to focus limited SNAP-Ed resources to reach as many of the SNAP-eligible, low-income population as possible, the Agency decided, as permitted by Section 28 of the Act, to define low-income individual to ease administrative burden on States to target eligible populations. The Secretary's definition for low-income persons for SNAP-Ed under this rule is SNAP participants and low-income individuals eligible to receive SNAP benefits or other means-tested Federal assistance programs such as Medicaid, Temporary Assistance for Needy Families (TANF), the free and reduced price meals under the National School Lunch Program (NSLP), etc. This definition of low-income more closely aligns SNAP-Ed with other FNS, Federal, and State-administered benefit programs, allowing the focus to remain on low-income populations while permitting a greater reach to persons residing in communities with a significant low-income population.

SNAP-Ed Plan Guidance prior to implementation of the HHFK Act provisions defined the target audience for services as SNAP participants and eligibles and included multiple strategies and data sources to assist agencies in identifying their target populations. Commenters stated that the strategies and data sources described in this previous SNAP-Ed Plan Guidance did not entirely address the challenges experienced by some agencies to identify and reach their target audience. They described the challenges some face in implementing interventions such as social marketing campaigns where, in focusing efforts on the low-income population, they inevitably reach ineligible persons. These stakeholders indicated that implementing SNAP-Ed activities should not exclude strategies States may develop that might include ineligible individuals while reaching significant numbers of low-income persons.

The Agency understands that States want greater flexibility in the methods and data sources they use to identify their low-income SNAP-Ed population to improve service delivery. FNS has determined that States may propose alternative targeting methodologies such as defined areas around a qualifying school, SNAP office, etc. that use relevant supporting data sources beyond those included in prior SNAP-Ed Plan Guidance to identify their target audience. States may propose how they will identify their target audience as that audience is defined in Section 28 of the Act and § 272.2(d)(2)(iii) of this rule. FNS will consider these State targeting proposals in SNAP-Ed Plans submitted for approval.

Use of Funds

FNS received a significant number of comments from stakeholders, including Federal partners, on the definition of nutrition education and obesity prevention services in SNAP-Ed under this rule. SNAP-Ed Plan Guidance prior to implementation of the HHFK Act provisions defined nutrition education in SNAP-Ed as follows.

Nutrition education is a set of learning experiences designed to facilitate the early adoption of eating and other nutrition-related behaviors conducive to health and well-being for those on a limited budget.

This definition addresses primarily the nutrition-related behavior of SNAP recipients who, by definition, have limited resources. Many stakeholders recommended revising this definition to address additional factors that impact individual health and well-being such as environmental, community, and policy factors that invariably impact food choices. A majority of stakeholders recommended using the following definition as the foundation for nutrition activities in SNAP:

Nutrition education is any combination of educational strategies, accompanied by environmental supports, designed to facilitate

voluntary adoption of food choices and other nutrition-related behaviors conducive to health and well-being; nutrition education is delivered through multiple venues and involves activities at the individual, community and policy levels. (Isobel R. Contento, Ph.D., Nutrition Education, Linking Research, Theory, and Practice, Jones and Bartlett Publishers, 2011)

The Agency also sought to describe obesity prevention services as these are called for under Section 28 of the Act. CDC uses in its programming this definition for obesity prevention services: ''interventions that address one or multiple levels of the socio-ecologic model (SEM) related to nutrition, physical activity, or select lifestyle behaviors that have been shown to impact obesity, and address that level through policy, system, and environmental supports''. In addition to CDC's definition, FNS considered some of the Institute of Medicine's key messages about obesity prevention to describe obesity prevention services in future SNAP-Ed programming such as ''The most promising approaches for obesity prevention are population-based and multilevel, focus on environmental and policy change, and require participation from actors in multiple sectors'' and ''The strategies and actions undertaken to prevent obesity and their resulting outcomes vary according to the different environments in which they are undertaken''. (Bridging the Evidence Gap in Obesity Prevention: A Framework to Inform Decision Making, Institute of Medicine, Food and Nutrition Board, April, 2010)

Section 28 of the FNA states that the nutrition education and obesity prevention grant program activities may include comprehensive multilevel interventions at multiple complementary organizational and institutional levels with opportunity for community and public health approaches. FNS decided to develop a definition for nutrition education and obesity prevention services for use in SNAP-Ed programming to include factors illuminated by Contento and others, described in the HHFK Act, and implemented by other Federal agencies and SNAP-Ed partners and stakeholders. The updated definition considers the resources available for nutrition education and obesity prevention services, the mission of FNS: ''To provide children and needy families better access to food and a more healthful diet through its food assistance programs and comprehensive nutrition education efforts;'' and the goal of SNAP-Ed: ''To improve the likelihood that persons eligible for SNAP will make healthy food choices within a limited budget and choose physically active lifestyles consistent with the current Dietary Guidelines for Americans and USDA food guidance.''

The definition of *nutrition education and obesity prevention services* that will become the basis for SNAP-Ed programming under this rule and SNAP-Ed Plan Guidance implementing the HHFK Act provisions follows:

SNAP nutrition education and obesity prevention services are any combination of educational strategies, accompanied by environmental supports, designed to facilitate voluntary adoption of food and physical activity choices and other nutrition-related behaviors conducive to the health and well-being of SNAP participants and low-income individuals eligible to participate in SNAP and other means-tested Federal assistance programs. Nutrition education and obesity prevention services are delivered through multiple venues and involve activities at the individual, community, and appropriate policy levels. Acceptable policy level interventions are activities that encourage healthier choices based on the current Dietary Guidelines for Americans.

Section 28 of the FNA also stipulated that allowable nutrition education and obesity prevention strategies be evidence-based. Commenters provided feedback to the Agency on what evidence-based approaches they thought would move SNAP-Ed into closer alignment with other governmental, institutional, community-based, and public health organizations. Stakeholders also encouraged FNS to approve and promote nutrition education and obesity prevention activities that showed promise that could be instrumental in demonstrating the effectiveness of a wide range of approaches in providing these activities.

FNS sought to formulate a definition for evidence-based to describe the types of activities that would be funded in order to have the greatest impact. The Agency reviewed definitions used by the Institute of Medicine and CDC when developing the following definition for evidence-based that will be used to describe nutrition education and obesity prevention activities in SNAP-Ed.

An *evidence-based approach for nutrition education and obesity prevention* is defined as the integration of the best research evidence with best available practice-based evidence. The best research evidence refers to relevant rigorous nutrition and public health nutrition research including systematically reviewed scientific evidence. Practice-based evidence refers to case studies, pilot studies, and evidence from the field on nutrition education interventions that demonstrate obesity prevention potential.

Evidence may be related to obesity prevention target areas, intervention strategies, and/or specific interventions. The target areas are identified in the current Dietary Guidelines for Americans. Intervention strategies are broad approaches to intervening on specific target areas. Interventions are a specific set of evidence-based, behaviorally–focused activities and/or actions to promote healthy eating and active lifestyles. Evidence-based allowable use of funds for SNAP-Ed include conducting and evaluating intervention programs, and implementing and measuring policy, systems, and environmental changes in accordance with SNAP-Ed Guidance.

Section 28 further stipulates that funds may be used for evidence-based activities using these approaches:

(1) Individual or group-based nutrition education, health promotion, and intervention strategies;

(2) Comprehensive, multi-level interventions at multiple complementary organizational and institutional levels;

(3) Community and public health approaches to improve nutrition.

The first approach, individual or group-based nutrition education efforts, has been the hallmark of most nutrition efforts conducted by FNS programs, including SNAP. Commenters acknowledged the importance of providing nutrition education, health promotion, and other intervention strategies to individuals and groups.

A significant number of commenters urged FNS to allow States to implement strategies that would address the second approach, comprehensive, multi-level interventions at multiple complementary organizational and institutional levels, included in Section 28 of the FNA. An example of this approach could include collaborating with schools and other organizations to improve the school nutrition environment including providing nutrition education classes and serving on school wellness committees. Commenters generally suggested that FNS consider the socio-ecological model (SEM) to address interventions. The majority of these commenters requested that FNS allow nutrition education and obesity prevention activities to emanate from all levels of the SEM. The SEM, as described in the 2010 DGAs, provides a framework that illustrates how spheres of influence including individual factors,

environmental settings, sectors of influence (government, public health and health care systems, agriculture, industry, and media), and social and cultural norms affect individual and family eating and physical activity choices.

Commenters indicated that using the SEM to provide nutrition education and obesity prevention activities will address the relationship between individuals, families, their environmental setting, and the various sectors of influence in addition to the impact of social and cultural norms and values. Commenters stated that using a comprehensive approach such as the SEM could further SNAP-Ed's collaborative efforts and that doing so would make SNAP-Ed's strategies more consistent with current public and private organizational recommendations for providing nutrition education and obesity/chronic disease prevention strategies.

The third approach for the use of nutrition education and obesity prevention grant funds is community and public health approaches to improve nutrition. Community and public health approaches, based on a definition used by CDC, are efforts that impact a large segment of the population rather than targeting the individual. Public health approaches can be targeted to low-income populations by focusing the interventions on settings with large proportions of low-income people such as schools, worksites, or other settings with a majority low-income population. Community-based approaches can take place in community centers, places of worship, community gardens, schools, farmers markets, food retail venues, etc. Community and public health programs, environmental strategies, and policies can impact larger numbers of people as opposed to individual and group-based nutrition education interventions alone which may impact a small number of people.

Stakeholders encouraged greater implementation of multilevel interventions and community and public health approaches into SNAP-Ed activities. They added that SNAP-Ed funds could be leveraged with other Federal and State funds for nutrition education and obesity prevention efforts to increase effectiveness and efficiency.

States may implement one or more of the approaches described in Section 28 of the FNA to deliver evidence-based nutrition education and obesity prevention activities in their SNAP-Ed programs. To improve program design, FNS encourages State agencies to integrate multiple approaches in implementing these activities. SNAP-Ed Plan Guidance will further describe how nutrition education and obesity prevention activities can be implemented in SNAP-Ed utilizing the approaches called for in Section 28 of the Act.

Coordination

Section 28 of the FNA stipulates that nutrition education and obesity prevention grant program projects may be coordinated with other public or privately funded health promotion or nutrition improvement strategies as long as the State agency retains administrative control of the projects. While FNS currently encourages States to connect nutrition education across programs and to collaborate and develop more integrated nutrition education approaches, commenters advised FNS to more strongly encourage or mandate that State agencies coordinate their SNAP-Ed activities with other projects in their State to the maximum extent possible. Commenters recommended that States coordinate these services with other State-administered Federal programs, State and Federal nutrition education and obesity prevention strategies, and community-based efforts as examples.

FNS recognizes the potential synergy of coordinating nutrition education and obesity prevention activities with public and private interventions aimed at encouraging healthier lifestyles for the low-income population. It also recognizes the potential impact of leveraging SNAP-Ed financial resources with that of other organizations to reach eligible individuals through multiple channels and varied approaches. FNS continues to encourage States to coordinate SNAP-Ed activities with other national, State, and local nutrition education and health promotion initiatives and interventions including those implemented by other FNS nutrition assistance programs. FNS has determined that States shall describe their coordination efforts in their SNAP-Ed Plans. States are strongly encouraged to coordinate activities and collaborate with community nutrition education and obesity prevention activities such as State Departments of Health and Education implementation of related State and Federally-funded programs. Such collaboration provides the capacity to implement activities through multiple spheres of the SEM. In accordance with Section 28 of the FNA, States shall continue to show in their Plans that the funding received from SNAP will remain under the administrative control of the State agency as they coordinate their activities with other organizations.

Funding

Section 28 of the FNA altered the manner in which funding is provided to States for nutrition education and obesity prevention services. When the statute was enacted, for fiscal year 2011 and thereafter, States receive 100 percent Federal funding through grants with no requirement for a State contribution or match.

FNS staff held several listening sessions with State SNAP directors and local project staff and an additional session that was coordinated through the American Public Human Services Association to hear their concerns about the SNAP provisions of the HHFK Act. The majority of State and local concerns focused on State allocations and how those allocations may have differed from the level of funding requested in approved FFY 2011 SNAP-Ed Plans, as well as other funding issues. Most of the comments came from States whose allocation was significantly less than the amount earlier approved in their FFY 2011 State plans. Additionally States:

- Questioned whether reallocation of funds from States that would not use their full allocation was feasible;
- Requested further explanation of the funding formula that would be used from FFY 2012 onward; and
- Inquired as to whether States could borrow against future allocations to help meet shortfalls.

Under Section 28 of the FNA, FNS has no discretion in how the funds are allocated as the language in the Act is prescriptive. Based on the funding formula used to determine allocations under Section 28, some States received a lower allocation than the level approved in their FFY 2011 SNAP–Ed Plan and considered this a cut in funding. Other States received a higher allocation than the amount approved previously for FFY 2011.

States inquired as to whether there would be a reallocation of funds as allowed in the statute, should some States surrender funds they could not use. FNS encouraged States to expend all available funds and does not anticipate a need for reallocation. States surrendering funds would be negatively impacted since their base allocation for the following fiscal year would be reduced by the amount of funds surrendered. The base allocation for States receiving funds would be increased by the same amount. No funds were surrendered or reallocated in FFY 2011 and some States had to decrease planned services due to funding limitations.

Based on the Act, FNS cannot allow States to borrow against future allocations as some States requested. The Agency provided financial technical guidance to States to address their other funding-related concerns through *implementing memoranda and responses to questions.*

FNS considered the impact on State and local agencies as a result of the funding changes. The overall effect is to lessen administrative burden by eliminating the requirement that States provide a 50 percent contribution or match and the associated documentation. Furthermore, by making the grant period of performance a two-year period rather than the previous one-year period, the FNS provides greater flexibility to State agencies and allows them to expend effectively and more fully the Federal funds available to them.

This rule implements financial changes retroactive to the beginning of FFY 2011 as required by law. Based on the statute, FNS allocated $375,000,000 in grant funding for FFY 2011 for nutrition education and obesity prevention services to the 52 State agencies that provided SNAP–Ed services based on an approved FFY 2009 SNAP–Ed Plan. From October 1, 2011, and thereafter, each State agency that submits an approved SNAP–Ed Plan will receive a Federal nutrition education and obesity prevention grant consisting of a base amount that reflects its share of national SNAP–Ed expenditure for FFY 2009 as reported in February 2010. The grants are the only source of Federal funds available from SNAP for nutrition education and obesity prevention services to States. Costs in excess of the grants are not eligible for Federal SNAP reimbursement.

For FFY 2012 and thereafter the funds are indexed for inflation and are adjusted to reflect any increases for the 12-month period ending the preceding June 30 in the Consumer Price Index (CPI) for All Urban Consumers published by the Bureau of Labor Statistics of the Department of Labor. FNS will make every effort to provide estimates to States of any increases in the CPI earlier than June 30th. These estimates will be based on projections contained in the annual President's Budget submission to Congress. The funding formula from FFY 2014 and thereafter factors in State shares of national SNAP participation in conjunction with State shares of the base 2009 national expenditures, building progressively to a 50/50 weighting in FFY 2018 and beyond. The allocations to States for nutrition education and obesity prevention grant program services are summarized as follows:

- For FFY 2011, 2012, 2013, funds allocated to States are in direct proportion to State expenditures for FFY 2009, as reported in February 2010;
- For 2014, 90 percent based on expenditures, plus 10 percent based on the State's share of national SNAP participants for the 12-month period February 1, 2012 to January 31, 2013;
- For 2015, 80 percent based on expenditures, plus 20 percent based on the State's share of national SNAP participants for the 12-month period February 1, 2013 to January 31, 2014;
- For 2016, 70 percent based on expenditures, plus 30 percent based on the State's share of national SNAP participants for the 12-month period February 1, 2014 to January 31, 2015;
- For 2017, 60 percent based on expenditures, plus 40 percent based on the State's share of national SNAP participants for the 12-month period February 1, 2015 to January 31, 2016; and,
- For 2018 and thereafter, 50 percent based on expenditures, plus 50 percent based on the State's share of national SNAP participants for the previous 12-month period ending January 31st.

FNS reserves its authority to reallocate funds as described in Section 28 of the Act. If the Agency determines that a State agency will not expend all of its funds or if a State elects to not receive its entire grant amount, FNS may reallocate the unexpended funds during the period for which the funding is available for new obligations at the Federal level to other States that have approved SNAP–Ed Plans, as appropriate, based upon criteria that the Agency may establish for such purposes. Reallocated funds received by a State will be considered part of its base 2009 allocation for the next fiscal year for the purpose of determining allocation; funds surrendered by a State shall not be considered part of its base 2009 allocation for the next fiscal year for the purpose of determining allocation.

If a State proposes during the SNAP–Ed planning process to surrender funds that they have no plans to obligate during the two year period of performance for the grants, FNS could potentially re-direct those surrendered funds to other States. At this time, FNS anticipates that no State would surrender funds due to the potential for negative impact on the State's allocation for the following year. No States surrendered funds during fiscal year 2011 and no reallocation criteria were needed.

States expressed an interest in exercising greater oversight over administration of their SNAP–Ed grants, especially in light of adoption of community and public health approaches and the requirement for greater coordination and collaboration with public and private partners. Some States and other stakeholders expressed interest in using SNAP–Ed funds to employ State staff to oversee administration and monitoring of the funds. Some States inquired about incorporating more competition in selection of sub grantees to implement nutrition education and obesity prevention services. For these and other reasons, States requested FNS provide further guidance on State-level administration of nutrition education and obesity prevention grants. FNS' role in the State administration of approved grant funds is limited to what is required by Federal law. FNS did clarify to States that they have discretion to choose to use any part of their SNAP–Ed grant funds or other State administrative funds to retain staff, such as a Registered Dietitian or credentialed nutrition service provider, to administer SNAP–Ed grant funding. States additionally have the authority to award funds to sub grantees, competitively or otherwise, according to State financial guidance. However, funds shall remain under the administrative control of the State agency.

Executive Order 12866 and Executive Order 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

This interim rule has been designated an ''economically significant regulatory action'' under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

Regulatory Impact Analysis

As required for all rules that have been designated as economically significant by the Office of Management and Budget (OMB), a Regulatory Impact Analysis (RIA) was developed for this interim rule. The following summarizes

the conclusions of the regulatory impact analysis:

Need for Action: The interim rulemaking is necessary to amend SNAP regulations to implement Section 28 of the FNA of 2008, as added by Section 241 of Public Law 111–296, the HHFK Act of 2010 signed on December 13, 2010, to award grants to States for the provision of nutrition education and obesity prevention programs.

Benefits: There are several benefits to the rule. In the past, the funding for SNAP-Ed was highly variable between years. With this rule, the funding will grow by the CPI–U, smoothing out the variation to a regular growth pattern. Secondly, the cost-sharing burden on States will decrease because they will no longer have a required funding match and may result in improved targeting of services and greater efficiencies since States will no longer have to seek matching funds in order to provide those services. The rule has an added benefit of supporting more comprehensive anti-obesity efforts as the use of funding has been expanded to include environmental approaches and policy level work in addition to nutrition education and health promotion. States will have the opportunity to implement comprehensive, multilevel interventions and use community-based and public health approaches to extend their efforts. *Federal Cost Reduction:* The new rule is expected to reduce Federal costs by $158 million in FY 2013 and $663 million in the five-year period between FY 2013 and FY 2017. When annualized at a discount rate of 7 percent, this yields an expected Federal cost reduction of $131 million per year.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601–612) requires agencies to analyze the impact of rulemaking on small entities and consider alternatives that would minimize any significant impacts on a substantial number of small entities. Pursuant to that review, it has been certified that this rule will not have a significant impact on a substantial number of small entities. Currently, 52 State agencies implement SNAP-Ed programs, and this rule institutes policy oversight and cost reductions required by statute.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, the Department generally must prepare a written statement, including a cost benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures by State, local, or tribal governments, in the aggregate, or the private sector, of $100 million or more in any one year. When such a statement is needed for a rule, Section 205 of the UMRA generally requires the Department to identify and consider a reasonable number of regulatory alternatives and adopt the most cost effective or least burdensome alternative that achieves the objectives of the rule.

This interim rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) for State, local and tribal governments or the private sector of $100 million or more in any one year. Thus, the rule is not subject to the requirements of sections 202 and 205 of the UMRA.

Executive Order 12372

SNAP is listed in the Catalog of Federal Domestic Assistance under 10.561. For the reasons set forth in the final rule at 7 CFR part 3015, subpart V and related Notice (48 FR 29115, June 24, 1983), SNAP is excluded from the scope of Executive Order 12372 which requires intergovernmental consultation with State and local officials.

Federalism Summary Impact Statement

Executive Order 13132 requires Federal agencies to consider the impact of their regulatory actions on State and local governments. Where such actions have federalism implications, agencies are directed to provide a statement for inclusion in the preamble to the regulations in accordance with Section (6)(b)(2)(B) of Executive Order 13132. This interim rulemaking is necessary to amend SNAP regulations to implement Section 28 of the FNA of 2008, as added by Section 241 of Public Law 111–296, the HHFK Act of 2010. USDA has considered the impact of this rule on State and local governments and has determined that this rule does not have federalism implication and does not impose substantial or direct compliance costs on State and local governments. Therefore, under Section 6(b) of the Executive Order, a federalism summary impact statement is not required.

Executive Order 12988

This interim rule has been reviewed under Executive Order 12988, Civil Justice Reform. This interim rule is intended to have preemptive effect with respect to any State or local laws, regulations, or policies which conflict with its provisions or which would otherwise impede its full and timely implementation. This rule is not intended to have retroactive effect unless so specified in the Effective Dates section of the final rule. Prior to any judicial challenge to the provisions of the final rule, all applicable administrative procedures must be exhausted.

Civil Rights Impact Analysis

FNS reviewed this interim rule in accordance with the Department Regulation 4300–4, ''Civil Rights Impact Analysis,'' to identify and address any major civil rights impacts the rule might have on minorities, women, and persons with disabilities, elderly, homeless, and persons with Limited English proficiency.

Executive Order 13175

E.O. 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on policies that have tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that 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. In late 2010 and the first half of 2011, USDA engaged in a series of consultative sessions to obtain input by Tribal officials or their designees concerning the impact of this rule on the tribe or Indian Tribal governments, or whether this rule may preempt Tribal law. Reports from these consultations will be made part of the USDA annual reporting on Tribal Consultation and Collaboration. USDA will respond in a timely and meaningful manner to all Tribal government requests for consultation concerning this rule and will provide additional venues, such as webinars and teleconferences, to periodically host collaborative conversations with Tribal officials or their designees concerning ways to improve this rule in Indian country.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. Chap. 35; see 5 CFR part 1320) requires OMB approve all collections of information by a Federal agency before they can be implemented. Respondents are not required to respond to any collection of information unless it displays a current valid OMB control number.

Information Collection for SNAP-Ed requirements will not change under this rule. This interim rule does not increase burden hours for State agencies in the

preparation of Nutrition Education Plans. Nutrition Education State Plan requirements are included in the State Plan of Operations, OMB 0584–0083, Program and Budget Summary Statement, and will not change with this rule.

Additionally, State requirements to report on the Education and Administration Reporting System (EARS) information collection form, OMB 0584–0542, will not change under this rule. FNS may determine that future revisions are needed. States will report FY 2013 EARS data by December 31, 2013 thereby negating the necessity for an Information Collection Request as part of this rule.

E-Government Act Compliance

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

Regulatory Impact Analysis

7 CFR part 272: Supplemental Nutrition Assistance Program Provisions of Title II of Public Law 111–296

Supplemental Nutrition Assistance Program: Nutrition Education and Obesity Prevention Grant Program Interim Rule

I. Statement of Need

The interim rulemaking is necessary to amend Supplemental Nutrition Assistance Program (SNAP) regulations to implement Section 28 of the Food and Nutrition Act (''FNA'' or the ''Act'') of 2008, as added by Section 241 of Public Law 111–296, the Healthy, Hunger-Free Kids Act of 2010 (HHFK Act), signed on December 13, 2010, to award grants to States for the provision of nutrition education and obesity prevention programs. The HHFK Act removes the existing nutrition education program under section 11(f) of the Food and Nutrition Act of 2008 (7 U.S.C. 2011 et seq.), commonly known as SNAP-Ed, and replaces it with the nutrition education and obesity prevention grant program, which will still be referred to as SNAP-Ed. The interim rule seeks to improve program operation and effectiveness by making it easier for States to administer while meeting the needs of the eligible low-income population. The interim rule provides State agencies with requirements for implementing Section 28 of the FNA including the grant award process and the formula for allocating the 100 percent Federal grant funding authorized under the Act to carry out nutrition education and obesity prevention services each fiscal year.

II. Summary of Impacts

The Department has estimated that the SNAP-Ed program provision of Section 28 of the FNA implemented in the interim rule will result in a reduction of Federal costs of $158 million in Federal fiscal year (FFY) 2013 and $663 million over the 5 years, FFY 2013 through FFY 2017. The Federal budget impacts are summarized below in Table 1; these estimates are categorized as transfers in the accounting statement that follows.

TABLE 1—SUMMARY OF FEDERAL BUDGET IMPACTS

In millions of dollars	FFY 2013	FFY 2014	FFY 2015	FFY 2016	FFY 2017	Total
Nutrition Education and Obesity Prevention Grant Program—Section 28 of the FNA	−$158	−$77	−$109	−$142	−$177	−$663
Total Cost	−$158	−$77	−$109	−$142	−$177	−$663

As required by OMB Circular A–4, in Table 2 below, we have prepared an accounting statement showing the annualized estimates of benefits, costs, and transfers associated with the provisions of this interim rule.

TABLE 2—ACCOUNTING STATEMENT

	Primary estimate	Year dollar	Discount rate	Period covered
Benefits				
Qualitative: Provisions in Section 28 will result in a reduction of Federal costs and will reduce administrative and financial burden for States, as well as improve the likelihood that low-income persons eligible for SNAP and other federal means-tested programs will make healthy lifestyle choices.				
Costs				
Annualized Monetized ($millions/year).				
Transfers				
Annualized Monetized ($millions/year)	−$131 −$132	2013 2013	7% 3%	FFY2013–2017
The first-year cost reduction for the Federal government is estimated at $158 million, with a total cost reduction of $663 million in the first five years. Impacts are already incorporated into the President's budget baseline.				
From the Federal Government to State SNAP Agencies.				

Analysis of Impacts

The cost estimates rely on assumptions about the future growth of SNAP Education (SNAP-Ed) approved [1] Federal funding in absence of the change contained in Section 28 of the Food and Nutrition Act. Between FFY 2009 and FFY 2010, the approved Federal funding for SNAP-Ed grew from $350.3 million to $379.6 million, an increase of 8 percent. The cost estimate assumes the same annual growth rate in future years.

The estimates of the cost of the SNAP-Ed program in future years are based on economic assumptions from the Office of Management and Budget (OMB) of the June value of the Not Seasonally Adjusted Consumer Price Index for All Urban Consumers (CPI–U).

Nutrition Education and Obesity Prevention Grant Program—Section 241

Discussion: Section 28 of the FNA changed the funding for SNAP-Ed. In the past, the Department would match all State funding designated for SNAP-Ed in their SNAP nutrition education state plan. As a result, the approved Federal funding varied substantially from year-to-year, from a low of $99 million in FFY 2000 to nearly $380 million in FFY 2010. The year-to-year percentage changes during that time had a range from a decline of 1 percent to an increase of 45 percent.

This interim rule provides grants to States through 100 percent Federal SNAP funding and requires no State contribution or match. Section 28 of the FNA permits financial contributions from State and private, as well as from other Federal programs when multi-level/organizational activities are covered, for nutrition education and obesity prevention program activities and FNS encourages States to seek these contributions to leverage their Federal SNAP investment.

Effect on Low-Income Families: The Department determined that the definition of eligible individuals under Section 28 of the FNA does not significantly change the population eligible for the previous SNAP-Ed programs. The implementation of the new SNAP-Ed program will continue SNAP's commitment to serving low-income populations while focusing on the critical problem of obesity, a major health concern. Implementation of the SNAP-Ed program allows coordinated services to be provided to participants in Federal assistance programs and other low-income persons. This action will broaden coordination and collaboration efforts and relationships in order to provide more flexibility to include a wider range of evidence-based intervention strategies. It will foster a more effective and comprehensive program to address the critical problem of obesity, especially its effects on low-income Americans. The goal of the SNAP-Ed Program is to improve the likelihood that persons eligible for SNAP will make healthy food choices within a limited budget and choose physically active lifestyles consistent with the current Dietary Guidelines for Americans (DGAs).

Federal Savings Impact: The new legislation intends to improve program funding and operations by creating a specific formula with a set growth pattern for a steady year-to-year increase. The HHFK Act specified that total funding for FFY 2011 would be $375,000,000 and that total funding for subsequent fiscal years is adjusted to reflect any increases for the 12-month period ending the preceding June 30 in the Not Seasonally Adjusted CPI–U published by the Bureau of Labor Statistics (BLS) of the Department of Labor. Subsequent to the HHFK Act, the American Taxpayer Relief Act of 2012 (ATRA), signed into law on January 2, 2013, authorized the total amount of SNAP-Ed funding that would be available for FFY 2012 through FFY 2015 and then subsequent fiscal years would be adjusted by the CPI–U as in the HHFK Act. The following cost analysis uses the funding authorized in ATRA for FFY 2013 to FFY 2015 and estimates of the CPI–U in future years from OMB to estimate funding in FFY 2016 and FFY 2017.

ATRA authorized $285,000,000 for SNAP-Ed in FY 2013. We estimate the approved Federal funding for SNAP-Ed in the absence of Section 28 of the FNA and ATRA for FFY 2013 at $442,768,187. We calculate this by taking the approved Federal funding amount for FFY 2011 ($379,602,355) and multiplying it by an estimated increase of 8 percent to get the FFY 2012 funding. The amount of $379,602,355 multiplied by 1.08 is $409,970,543, which is the FFY 2012 funding. The FFY 2013 funding is calculated the same way. We multiply the FFY 2012 funding of $409,970,543 by 8 percent for a FFY 2013 funding total of $442,768,187.

To estimate the savings from implementing the new SNAP-Ed program funding formula, we subtract the SNAP-Ed program funding for FFY 2013 of $285,000,000 from the projected approved Federal funding for SNAP-Ed in absence of Section 28 of the Act and ATRA of $442,768,187. When we subtract $285,000,000 from $442,768,187, it results in a savings of $157,768,187 in FFY 2013.

The same methodology was used for FFY 2014 and FFY 2015. We calculated the funding for SNAP-Ed in absence of Section 28 of the FNA by multiplying the prior year's funding by 8 percent. The SNAP-Ed funding authorized in ATRA is $401,000,000 in FFY 2014 and $407,000,000 in FFY 2015. The difference between the two projected funding estimates is the savings in each fiscal year. This results in a savings of $77,189,642 in FFY 2014 and $109,444,813 in FFY 2015.

For FFY 2016, the SNAP-Ed funding authorized by ATRA is the prior year funding amount indexed by the change in the June value of the CPI–U. The OMB estimate of the unadjusted index is 240.229 for June 2014 and 245.513 for June 2015. To calculate the June-to-June change, we divide 245.513 by 240.229, which is 1.022. We then multiply the FFY 2015 funding amount of $407,000,000 by the June-to-June change in the CPI–U, or 1.022, which results in the FFY 2016 funding for SNAP-Ed of $415,952,241. When we subtracted this value from the projected funding for SNAP-Ed in absence of the HHFK Act for FFY 2016 of $557,760,398, the result is a savings of $141,808,157.

For FFY 2017 the SNAP-Ed funding for FFY 2016 is indexed by the change in the June value of the CPI–U. The OMB estimate of the unadjusted index is 250.915 for June 2016. To calculate the June-to-June change, we divide 250.915 by 245.513, which is 1.022. We then multiply the FFY 2016 funding amount of $415,952,241 by the June-to-June change in the CPI–U, or 1.022, which results in the FFY 2017 funding of $425,104,400. When we subtracted this value from the projected funding for SNAP-Ed in absence of the HHFK Act and ATRA for FFY 2016 of $602,381,230, the result is a savings of $177,276,830.

We anticipate that stabilizing the funding structure for SNAP nutrition education will save the Government $158 million in FFY 2013, and $663 million in the five-year period from FFY 2013 to FFY 2017.

Participant Impacts: We do not anticipate any changes in SNAP participation resulting from the SNAP-Ed Programs.

III. Alternatives Considered

Under Section 28 of the Food and Nutrition Act, the Department has no discretion in the total funding for SNAP-Ed programs or how the funds are allocated to the States as the language in the Act is prescriptive.

[1] Actual expenditures were often less than approved Federal funds.

Section 28 of the Food and Nutrition Act makes no significant change to the eligible population for SNAP-Ed programs.

We considered a number of alternatives for estimating future SNAP-Ed funding in absence of Section 28 of the FNA to determine the savings from the implementation of the SNAP-Ed programs. Because approved Federal funding for SNAP-Ed from year to year between FFY 2000 and FFY 2010 varied considerably, we could have used the average year-to-year change in funding based on actual dollar amounts, or we could have used an average year-to-year change in funding based on the percentage change. Another alternative we considered was using the compound annual growth rate in approved Federal funding. However, because the year-to-year funding amount changed considerably during that period, and because the amounts were decreasing over time, we chose to use only the change of 8 percent between the most recent two fiscal years, FFY 2009 and FFY 2010, which reflects a conservative estimate of future growth in SNAP-Ed funding in the absence of Section 28 of the FNA.

IV. References

Approved Federal Funds for Supplemental Nutrition Assistance Program Education by Fiscal Year at *http://www.nal.usda.gov/foodstamp/pdf/Historical%20FSNE%20Funding.pdf* and *http://www.nal.usda.gov/foodstamp/pdf/Historical%20FSNE%20Funding.pdf*.

Bureau of Labor Statistics Consumer Price Index page at *http://www.bls.gov/cpi/*.

List of Subjects in 7 CFR Part 272

Alaska, Civil rights, Supplemental Nutrition Assistance Program, Grant programs-social programs, Reporting and recordkeeping requirements, Unemployment compensation, Wages.

For the reasons set forth in the preamble, 7 CFR part 272 is amended as follows:

PART 272—REQUIREMENTS FOR PARTICIPATING STATE AGENCIES

■ 1. The authority citation for part 7 CFR part 272 continues to read as follows:

Authority: 7 U.S.C. 2011–2036.

■ 2. In § 272.2, paragraphs (d)(1)(iii), (d)(2), (d)(6) are revised to read as follows:

§ 272.2 Plan of operation.

* * * * *

(d) * * *

(1) * * *

(iii) Nutrition Education Plan if the State agency elects to request Federal Supplemental Nutrition Assistance Program Education (SNAP-Ed) grant funds to conduct nutrition education and obesity prevention services as discussed in paragraph (d)(2) of this section.

* * * * *

(2) Nutrition Education Plan. If submitted, the Supplemental Nutrition Assistance Program Education (SNAP-Ed) Plan shall:

(i) Conform to standards established in this regulation, SNAP-Ed Plan Guidance, and other FNS policy. A State agency may propose to implement an annual or multiyear Plan of up to three years;

(ii) Identify the methods the State will use to notify applicants, participants, and eligible individuals to the maximum extent possible of the availability of SNAP-Ed activities in local communities;

(iii) Describe the nutrition education and obesity prevention services that the State will provide in SNAP-Ed and how the State will deliver those services, either directly or through agreements with other State or local agencies or community organizations;

(iv) Ensure interventions are appropriate for the low-income population defined as SNAP participants and low-income individuals eligible to receive SNAP benefits or other means-tested Federal assistance programs. The interventions must recognize the population's constrained resources and potential eligibility for Federal food assistance;

(v) Describe methods the State agency will use to identify its target audience. FNS will consider for approval targeting strategies and supporting data sources included in SNAP-Ed Plan Guidance and alternate targeting strategies and supporting data sources proposed by State agencies;

(vi) *Use of Funds.* (A) A State agency must use the SNAP-Ed nutrition education and obesity prevention grant to fund the administrative costs of planning, implementing, and operating its SNAP-Ed program in accordance with its approved SNAP-Ed Plan;

(B) *Definitions.* SNAP nutrition education and obesity prevention services are defined as any combination of educational strategies, accompanied by environmental supports, designed to facilitate voluntary adoption of food and physical activity choices and other nutrition-related behaviors conducive to the health and well-being of SNAP participants and low-income individuals eligible to participate in SNAP and other means-tested Federal assistance programs. Nutrition education and obesity prevention services are delivered through multiple venues and involve activities at the individual, community, and appropriate policy levels. Acceptable policy level interventions are activities that encourage healthier choices based on the current Dietary Guidelines for Americans; SNAP-Ed nutrition education and obesity prevention activities must be evidence-based. An evidence-based approach for nutrition education and obesity prevention is defined as the integration of the best research evidence with best available practice-based evidence. The best research evidence refers to relevant rigorous nutrition and public health nutrition research including systematically reviewed scientific evidence. Practice-based evidence refers to case studies, pilot studies, and evidence from the field on nutrition education interventions that demonstrate obesity prevention potential. Evidence may be related to obesity prevention target areas, intervention strategies, and/or specific interventions. The target areas are identified in the current Dietary Guidelines for Americans. Intervention strategies are broad approaches to intervening on specific target areas. Interventions are a specific set of evidence-based, behaviorally-focused activities and/or actions to promote healthy eating and active lifestyles. Evidence-based allowable uses of funds for SNAP-Ed include conducting and evaluating intervention programs, and implementing and measuring policy, systems, and environmental changes in accordance with SNAP-Ed Guidance;

(C) SNAP-Ed activities must promote healthy food and physical activity choices based on the most recent Dietary Guidelines for Americans.

(D) SNAP-Ed activities must include evidence-based activities using one or more of these approaches: individual or group-based nutrition education, health promotion, and intervention strategies; comprehensive, multi-level interventions at multiple complementary organizational and institutional levels; community and public health approaches to improve nutrition;

(vii) Include a description of the State's efforts to coordinate activities with national, State, and local nutrition education and health promotion initiatives and interventions, whether public or privately funded. The relationship between the State agency

and other organizations it plans to coordinate with for the provision of services, including statewide organizations must be described. Copies of contracts and Memoranda of Agreement must be available for inspection upon request;

(viii) Include an operating budget for the Federal fiscal year with an estimate of the cost of operation for one or more years, according to the State's approved SNAP-Ed Plan;

(ix) *Federal financial participation and allocation of grants.* (A) Each State agency that submitted an approved fiscal year 2009 SNAP-Ed Plan will receive a 100 percent Federal grant each fiscal year to operate SNAP-Ed based on the State's share of national SNAP-Ed expenditures for fiscal year 2009 as reported in February 2010. The grant requires no State contribution or match. The grant period of performance is two years and these funds are the only source of Federal funds available under the Food and Nutrition Act of 2008, as amended, for SNAP nutrition education and obesity prevention services to States. Funds in excess of the grants are not eligible for SNAP Federal reimbursement;

(B) A State agency's receipt of its 100 percent Federal SNAP-Ed grant is contingent on FNS' approval of the State agency's SNAP-Ed Plan. If an adequate Plan is not submitted, FNS may reallocate a State agency's grant among other State agencies with approved Plans;

(C) States shall identify the uses of funding for local projects and show that the funding received shall remain under the administrative control of the State agency;

(D) Annually, FNS will determine each State's share of the funding provided for each fiscal year. The amount of funding provided in fiscal year 2011 was $375,000,000, and the amount of funding provided in each subsequent year is determined by adjusting the previous fiscal year's amount to reflect any increases for the 12-month period ending the preceding June 30th in the Consumer Price Index for All Urban Consumers published by the Bureau of Labor Statistics of the Department of Labor;

(E) FNS will allocate the funding available each fiscal year for SNAP-Ed grants using the formula proscribed by law that factors in State shares of the base 2009 Federal expenditures, building progressively to a 50/50 weighting of expenditures to participation from fiscal year 2014 to fiscal year 2018 and beyond. The allocations to a State for SNAP-Ed grants will be:

(*1*) For fiscal year 2013, in direct proportion to State expenditures for FFY 2009, as reported in February 2010;

(*2*) For fiscal year 2014, 90 percent based on expenditures, plus 10 percent based on the State's share of national SNAP participants for the 12-month period February 1, 2012 to January 31, 2013;

(*3*) For fiscal year 2015, 80 percent based on expenditures, plus 20 percent based on the State's share of national SNAP participants for the 12-month period February 1, 2013 to January 31, 2014;

(*4*) For fiscal year 2016, 70 percent based on expenditures, plus 30 percent based on the State's share of national SNAP participants for the 12-month period February 1, 2014 to January 31, 2015;

(*5*) For fiscal year 2017, 60 percent based on expenditures, plus 40 percent based on the State's share of national SNAP participants for the 12-month period February 1, 2015 to January 31, 2016; and,

(*6*) For fiscal year 2018 and thereafter, 50 percent based on expenditures, plus 50 percent based on the State's share of national SNAP participants for the previous 12-month period ending January 31;

(F) If a participating State agency notifies FNS that it will not obligate or expend all of the funds allocated to it for a fiscal year under this section, FNS may reallocate the unobligated, unexpended funds to other participating State agencies that have approved SNAP-Ed Plans during the period for which the funding is available for new obligations at the Federal level. Reallocated funds received by a State will be considered part of its base 2009 allocation for the next fiscal year for the purpose of determining allocation; funds surrendered by a State shall not be considered part of it base 2009 allocation for the next fiscal year for the purpose of determining allocation.

(x) *Fiscal recordkeeping and reporting requirements.* Each participating State agency must meet FNS fiscal recordkeeping and reporting requirements. Total SNAP-Ed expenditures are reported on the Financial Status Report (SF–425). States are expected to continue to collect and report State and private contributions to their SNAP-Ed activities through the Education Administration and Reporting System FNS–759;

(xi) Additional information may be required of the State agency, on an as needed basis, regarding the type of nutrition education and obesity prevention activities offered and the characteristics of the target population served, depending on the contents of the State's SNAP-Ed Plan, to determine whether nutrition education goals are being met;

(xii) The State agency must submit a SNAP-Ed Annual Report to FNS by November 30th of each year. The report shall describe SNAP-Ed Plan project activities and budget for the prior year.

* * * * *

(e) * * *

(6) The SNAP-Ed Plan shall be signed by the head of the State agency and submitted prior to funding of nutrition education and obesity prevention activities when the State agency elects to request Federal grant funds to conduct these SNAP-Ed activities. The Plan shall be submitted for approval no later than August 15th. Approved plans become effective the following FFY October 1st to September 30th.

* * * * *

§ 272.5 [Amended]

■ 4. Section 272.5(b)(1) is amended by removing paragraphs (b)(1) and (b)(2) and redesignating paragraphs (b)(3) and (b)(4) as paragraphs (b)(1) and (b)(2).

Dated: March 27, 2013.

Kevin Concannon,

Under Secretary, Food, Nutrition, and Consumer Services.

[FR Doc. 2013–07602 Filed 4–4–13; 8:45 am]

BILLING CODE 3410–30–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

14 CFR Part 1209

[Docket No. NASA–2013–0001]

RIN 2700–AD82

Boards and Committees

AGENCY: National Aeronautics and Space Administration.

ACTION: Direct final rule.

SUMMARY: This direct final rule makes nonsubstantive changes to correct and remove citations referenced in NASA's Contract Adjustment Board rule. The revision to this rule is part of NASA's retrospective plan under Executive Order (EO) 13563 completed in August 2011. NASA's full plan and updates can be accessed on the Agency's open Government Web site at *http://www.nasa.gov/open/.*

DATES: This direct final rule is effective on June 4, 2013. Comments due on or before May 6, 2013. If adverse comments are received, NASA will publish a timely withdrawal of the rule in the **Federal Register**.

ADDRESSES: Comments must be identified with RIN 2700–AD82 and may be sent to NASA via the *Federal E-Rulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Please note that NASA will post all comments on the Internet with changes, including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Nanette Jennings, (202) 358–0819.

SUPPLEMENTARY INFORMATION:

Direct Final Rule Adverse Comments

NASA has determined this rulemaking meets the criteria for a direct final rule because it involves nonsubstantive changes to correct citations. No opposition to the changes and no significant adverse comments are expected. However, if the Agency receives a significant adverse comment, it will withdraw this direct final rule by publishing a notice in the **Federal Register**. A significant adverse comment is one that explains: (1) Why the direct final rule is inappropriate, including challenges to the rule's underlying premise or approach; or (2) why the direct final rule will be ineffective or unacceptable without a change. In determining whether a comment necessitates withdrawal of this direct final rule, NASA will consider whether it warrants a substantive response in a notice and comment process.

Background

The Board, established on May 15, 1961, is authorized to act for and exercise the authority of the Administrator in cases involving requests for extraordinary contractual adjustments under the Act of August 28, 1958 (50 U.S.C. 1431–35), is continued in effect by this regulation. Subpart 3 was promulgated to consider and dispose of requests for extraordinary contractual adjustments by contractors of NASA. The Board references an obsolete internal NASA policy (NASA Management Instruction (NMI) 1152.5) that was cancelled September 30, 1994, because it was considered to be a duplication of this regulation. Therefore, it should no longer be referenced in the regulation.

Statutory Authority

The National Aeronautics and Space Act (the Space Act), 51 U.S.C. 20113(a), authorizes the Administrator of NASA to make, promulgate, issue, rescind, and amend rules and regulations governing the manner of its operations and the exercise of the powers vested in it by law.

Regulatory Analysis

Executive Order 12866, Regulatory Planning and Review and Executive Order 13563, Improvement Regulation and Regulation Review

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). EO 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated as ''not significant'' under section 3(f) of EO 12866.

Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires an agency to prepare an initial regulatory flexibility analysis to be published at the time the proposed rule is published. This requirement does not apply if the agency ''certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities'' (5 U.S.C. 603). This rule removes an obsolete citation referenced in 14 CFR part 3 and, therefore, does not have a significant economic impact on a substantial number of small entities.

Review Under the Paperwork Reduction Act

This direct final rule does not contain any information collection requirements subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Review Under EO 13132, Federalism

EO 13132, ''Federalism,'' 64 FR 43255 (August 4, 1999) requires regulations be reviewed for Federalism effects on the institutional interest of states and local governments, and if the effects are sufficiently substantial, preparation of the Federal assessment is required to assist senior policy makers. The amendments will not have any substantial direct effects on State and local Governments within the meaning of the EO. Therefore, no Federalism assessment is required.

List of Subjects in 14 CFR Part 1209

Government contracts.

Accordingly, 14 CFR part 1209, subpart 3 is revised as follows:

PART 1209—BOARDS AND COMMITTEES

■ 1. The authority citation for part 1209 subpart 3 is revised as follows:

Authority: Pub. L. 85–804 and 51 U.S.C. 20113.

§ 1209.302 [Amended]

■ 2. In § 1209.302, remove the words ''NASA Management Instruction (NMI) 1152.5 and''.

Charles F. Bolden, Jr.,

Administrator.

[FR Doc. 2013–07962 Filed 4–4–13; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE INTERIOR

Bureau of Safety and Environmental Enforcement

30 CFR Part 250

[Docket ID: BSEE–2012–0011]

RIN 1014–AA04

Oil and Gas and Sulphur Operations in the Outer Continental Shelf—Revisions to Safety and Environmental Management Systems

AGENCY: Bureau of Safety and Environmental Enforcement (BSEE); Interior.

ACTION: Final rule.

SUMMARY: This final rule will revise and add several new requirements to regulations for Safety and Environmental Management Systems (SEMS). These requirements pertain to developing and implementing stop work authority (SWA) and ultimate work authority (UWA), requiring an employee participation plan (EPP), and establishing guidelines for reporting unsafe working conditions. The rule establishes additional requirements for conducting job safety analyses (JSA) for activities identified in an operator's SEMS program. In addition, this final rule requires that SEMS programs be audited by an accredited audit service provider (ASP). This rulemaking will further support BSEE's efforts to reduce the occurrence of accidents, injuries, and spills during oil and gas activities on the Outer Continental Shelf (OCS).

DATES: This rule becomes effective on June 4, 2013. You must comply with the provisions of this rule on or before June 4, 2014, except the auditing requirements under § 250.1920. You must be in compliance with § 250.1920 by June 5, 2015. The incorporation by reference of certain publications listed

in the rule is approved by the Director of the Federal Register as of June 4, 2013.

FOR FURTHER INFORMATION CONTACT: Keith Petka, Office of Offshore Regulatory Programs, (703) 787–1736 or email *sems@bsee.gov.*

SUPPLEMENTARY INFORMATION:

Executive Summary

When Congress enacted the Outer Continental Shelf Lands Act (OCSLA) (43 U.S.C. 1332(6)), it declared that it is the policy of the United States to assure that operations on the OCS are conducted:

- Safely by well-trained personnel; and
- Using technology, precautions, and techniques sufficient to prevent or minimize the likelihood of:
  - blowouts, loss of well control, fires, or spillage, physical obstruction to other users of the waters or subsoil and seabed;
  - occurrences that may cause damage to the environment or to property; and
  - occurrences that endanger life or health.

Final regulations implementing a SEMS program were published on October 15, 2010, to accomplish these goals and to reduce the likelihood of another event like the *Deepwater Horizon* explosion and oil spill, 75 FR 63610. The regulations required operators to have a SEMS program in place as of November 15, 2011. A SEMS program is a comprehensive system to reduce human error and organizational failure.

On September 14, 2011, the Bureau of Ocean Energy Management, Regulation and Enforcement (BOEMRE) published a Notice of Proposed Rulemaking in the **Federal Register** entitled, ''Oil and Gas and Sulphur Operations in the Outer Continental Shelf—Revisions to Safety and Environmental Management Systems'' (76 FR 56683). These revisions to 30 CFR 250, subpart S, grow out of and strengthen the existing SEMS framework. The previous SEMS final rule was published in October 2010. The current BSEE SEMS regulations incorporate by reference the entirety of the American Petroleum Institute's Recommended Practice 75 (API RP 75), Third Edition, May 2004, reaffirmed May 2008. Many companies operating on the OCS were already in compliance with parts of the existing SEMS regulation when it was published in 2010. Through this final rule, being published today, BSEE supplements the requirements in API RP 75 to ensure that all companies are implementing current best practices and establishing well-functioning SEMS programs.

This final rule incorporates ideas from comments that were received following publication of the proposed rule. This final rule will require operators to integrate new requirements into their existing SEMS program to enhance the program and facilitate oversight. These additional requirements provide several key ways for personnel to help ensure safe performance of oil and gas activities on the OCS:

1. *Job Safety Analysis (JSA)*—Provides additional requirements for conducting a JSA.
2. *Auditing*—Requires that all SEMS audits must be conducted by an audit service providers (ASPs), accredited by a BSEE-approved accreditation body (AB).
3. *Stop Work Authority (SWA)*—Creates procedures that establish SWA and make responsible any and all personnel who witness an activity that is creating imminent risk or danger to stop work.
4. *Ultimate Work Authority (UWA)*—Clearly defines requirements establishing who has the UWA on the facility for operational safety and decision-making at any given time.
5. *Employee Participation Plan (EPP)*—Provides an environment that promotes participation by employees and management in order to eliminate or mitigate hazards on the OCS.
6. *Reporting Unsafe Working Conditions*—Empowers all personnel to report to BSEE possible violations of safety or environmental regulations and requirements and threats of danger.

Background

Pursuant to the OCSLA, the Federal government has a broad mandate to promote a culture of safety and environmental protection on the OCS. Acting on this mandate, BSEE's predecessor, the Minerals Management Service (MMS), advocated voluntary implementation of API RP 75. The MMS' goal was to assist in the development of a management system designed to promote safety and environmental protection during the performance of offshore oil and gas and sulphur operations. This system would be a tool for integrating and managing operations. By developing a management system based on API RP 75, owners and operators would be required to formulate policy and objectives concerning significant safety hazards and environmental impacts over which they had control and could be expected to have an influence. Ultimately, a SEMS program is intended to focus attention on the role of human error and poor organization in accidents, drive continuous improvement in the offshore industry's safety and environmental records, encourage the use of performance-based operating practices, and encourage collaboration between industry to promote the interests of offshore worker safety and environmental protection.

Many operators voluntarily developed a SEMS program, as outlined by API RP 75. Prior to implementing the SEMS regulations, MMS carefully analyzed accident panel investigation reports, incident reports, and incidents of noncompliance. The MMS determined that the root cause of most safety and environmental accidents and incidents derived from four specific elements identified in API RP 75: Hazards Analysis; Management of Change; Operating Procedures; and Mechanical Integrity. The MMS issued an Advance Notice of Proposed Rulemaking on May 22, 2006 (71 FR 29277), soliciting comments on amending the agency's regulations to include SEMS. The MMS issued a Notice of Proposed Rulemaking on June 17, 2009 (74 FR 28639) that would require all operators to develop a management system minimally consisting of the four main elements identified by MMS as the root cause of most accidents.

However, the *Deepwater Horizon* explosion and resulting oil spill highlighted potential faults in the existing OCS safety culture, convincing MMS of the need to require all operators to implement a comprehensive SEMS. On October 15, 2010, BOEMRE, the successor agency to MMS, published in the **Federal Register** the final rule, ''Oil and Gas and Sulphur Operations in the Outer Continental Shelf—Safety and Environmental Management Systems'' (75 FR 63610). That rule established a new Subpart S in 30 CFR part 250, requiring all OCS operators to have a SEMS program in place by November 15, 2011.

Nearly a month before this deadline, on September 14, 2011, BOEMRE proposed revisions to SEMS to address safety concerns that were not covered in the first SEMS final rule issued in October 2010. The comment period for the proposed rule closed on November 14, 2011. In this final rule, BSEE is promulgating many of the changes that were proposed in the September 2011 proposed rule.

On June 21, 2010, the MMS was renamed to BOEMRE. On October 1, 2011, the Department of the Interior (DOI) reorganized BOEMRE, creating two new Bureaus, BSEE and the Bureau of Ocean Energy Management (BOEM).

The SEMS program and regulations fall under the authority of BSEE.

Summary of Comments on the Notice of Proposed Rulemaking

In response to the proposed rule, BSEE received 35 sets of comments from oil and gas companies (operators and contractors), industry associations, environmental organizations, and individuals. In the following section, we first address the general comments on the rule. These are followed by a Section-by-Section discussion of comments, including any changes made to the final rule based on comments. Comments that are not related to the proposed rule or that are outside the scope of this rulemaking are not addressed. All of the comments received are posted on *www.regulations.gov,* under docket number BOEM–2011–0003.

General Comments

Comment: A commenter suggested that BSEE reopen the comment period and hold a workshop to address the following issues:

(1) The BSEE's vision for the regulatory program.

(2) The BSEE's strategy for achieving that vision.

(3) Migrating to a goal-setting regime that is less prescriptive, with fewer approvals.

(4) How SEMS ''fits'' with the United States Coast Guard (USCG) and Pipeline and Hazardous Materials Safety Administration (PHMSA).

(5) How the SEMS regulations compare to other international regulatory regimes.

(6) Experience with implementation of SEMS to date.

Several other commenters also requested more time to comment on the proposed rule.

Response: The BSEE does not believe it is necessary to allow more time to comment on the proposed rule. In the future, we intend to hold a workshop on SEMS to address implementation and other issues raised in the comments. The BSEE actively engages with members of the industry, non-government organizations, academia, trade organizations, standards committees, and members of the public to develop regulations and standards, and to encourage joint participation in research and workshops. All of these activities are used to implement BSEE's vision for safe, clean, and efficient OCS operations.

Comment: A commenter stated that the proposed rule appeared to indicate that a company's size does not matter in relation to safety, and that adverse consequences from an incident are the same regardless of the operator's size. Instead, the commenter felt that smaller operators have fewer financial resources compared to large operators. The commenter stated that in the event of a catastrophic incident, a small operator is more likely to seek bankruptcy protection and walk away from the problem than a larger operator. Additionally, the commenter believes the main lesson to be learned from the *Deepwater Horizon* explosion and oil spill is that the risk of another event stems from managing high pressure wells, not from operating in deepwater.

Response: The BSEE disagrees that a small operator is more likely to walk away from a catastrophic incident than a larger operator. We stated in the Notice of Proposed Rulemaking that ''adverse consequences in the event of incidents are the same regardless of the operator's size.'' This statement reflects BSEE's concern that small, mid-size, or large OCS oil and gas operators working on the shelf or in deepwater on high-pressure or normal pressure wells can cause damage and loss of life resulting from an oil spill, fire, or explosion. Regarding small companies that declare bankruptcy, the OCSLA authorizes DOI to require lessees to provide financial assurance to cover their decommissioning obligations. Should a small operator attempt to avoid liability for a catastrophic incident, existing statutes govern the agency's rights in that proceeding.

Comment: Some commenters urged BSEE to withdraw the proposed rulemaking and reconsider its approach toward using SEMS on the OCS. One commenter stated that the existing BSEE SEMS rule is flawed and expressed concern over the UWA, the definition of facility, contractor responsibilities and liabilities, and jurisdictional boundaries. A wide range of industry commenters also raised concerns regarding the jurisdiction of other Federal agencies. The commenters believed that the scope of the SEMS program should not be defined by Memoranda of Agreement (MOAs) and Memoranda of Understanding (MOUs) among Federal agencies. There is concern that ''unscrupulous'' parties may ''severely restrict'' their SEMS programs based on jurisdictional issues. Some commenters believe that the phrase ''activities that are regulated under BSEE jurisdiction'' creates ''considerable and unacceptable ambiguity.'' Some commenters believe that problems caused by jurisdictional questions can be avoided if SEMS takes a ''holistic'' approach to OCS safety regulations.

Response: The BSEE has authority under the OCSLA to regulate safety and environmental matters associated with oil and gas development. Accordingly, BSEE's authority under the OCSLA is not limited simply because BSEE authority coincides with the authority of another government agency. In a number of areas, BSEE co-regulates offshore activity with other Federal agencies, such as the Coast Guard and EPA. None of the provisions of this rule affects or modifies the authority of these other agencies. The BSEE uses MOUs and MOAs with other agencies to coordinate the regulatory activities for specific types of equipment and processes, but these interagency agreements do not limit the scope of the SEMS program that must be maintained by the operator under these regulations. An operator's SEMS program should address all oil and gas activities subject to a lease and should not be limited to the components listed in the interagency agreements. To further clarify, BSEE has removed the phrase ''activities that are regulated under BSEE jurisdiction'' from the final rule.

The concerns raised by the comments about UWA, definitions, and potential contractor liabilities are addressed in the Section-by-Section discussion. The BSEE also addresses certain minor editorial flaws and redundancies in the existing regulation. For example, § 250.1920 now consolidates the audit frequency information into one subsection in order to improve readability.

Comment: Another commenter expressed the view that the proposed rule has many elements requiring hazard recognition and formal reporting of unsafe conditions. Therefore, the commenter urged BSEE to consider including a requirement for operators to conduct and submit an independent, anonymous survey that validates the status of the existing safety culture, at least once every three years. The commenter believed that this proposed survey would provide evidence for how well the components of work stoppage, employee empowerment, employee participation, etc., have become engrained within the operating culture. The commenter stated that the results would provide further opportunities for initiating action planning and remedial measures. The commenter asserted that it would represent a viable ''link'' between the SEMS provisions and the reality of how those SEMS components need to be incorporated within a healthy safety culture.

Response: The BSEE sees value in the comment concerning a periodic submission of a ''survey'' to validate the

existence and status of a safety culture within an operator's organization. The BSEE will take this comment under consideration for future guidance or future rulemaking. Such a requirement could be put into effect by BSEE in the future.

Contractor Safety and Environmental Management Systems Program

Comment: Several comments stated that BSEE should better address the role of contractors in the SEMS program. There were suggestions to clarify the regulation regarding the role of contractors in improving safety and environmental performance. The comments also proposed that contractors should have their own separate SEMS and it should not be the operator's role to ensure that contractor employees are trained in the operator's SEMS program.

Response: In response to these comments, BSEE is evaluating the possibility of requiring contractors to have a SEMS program while performing operations on the OCS. The BSEE may address this concept through future rulemaking. Currently, all personnel, which includes contractors, must be trained in accordance with the requirements of § 250.1915. Operators must verify that contractors are trained in accordance with § 250.1915 prior to performing a job. In accordance with § 250.1914, operators must ensure that contractors have their own written safe work practices. Contractors may adopt appropriate sections of an operator's SEMS program. Operators and contractors must document an agreement on appropriate contractor safety and environmental policies and practices before the contractor begins work at an operator's facilities.

Comment: The commenter stated that BSEE needs to explore the possibility of developing regulations that ensure worker and contractor qualifications (as in the Transportation of Hazardous Liquids by Pipeline (49 CFR part 195, subpart G)) in addition to including training requirements in the SEMS program. The commenter also stated that it is not enough for workers to be trained; the workers need to prove their capabilities and document the proof.

Response: A SEMS program, under the existing regulations, must ensure that all personnel are trained in accordance with their duties and responsibilities to work safely and are aware of potential environmental impacts. Because technologies and practices change, and circumstances are diverse, BSEE favors a flexible approach. In the future, BSEE may consider a more prescriptive approach for establishing worker qualifications and evidence of capabilities.

Process Safety

Comment: A few commenters stated that BSEE should explore the question of whether the Occupational Safety and Health Administration's (OSHA) Process Safety Management (PSM) program will provide a superior approach to attaining process safety compared to the SEMS approach. The commenters stated that if PSM data shows a significant and meaningful reduction in process safety accidents, BSEE should consider implementing PSM requirements or incorporate elements of such an approach into future SEMS rulemakings.

Another commenter stated that the proposed regulations do not fully draw upon the learning and best practices from PSM to handle low-probability, high-consequence events that often become large disasters. The commenter believes that process safety requires more than a SEMS program and the new elements. The commenter proposed that BSEE regulations should also address safety critical elements and performance requirements for those elements. Additionally, the commenter stated that BSEE regulations should ensure that barrier management for all operations is identified, described, and managed based upon process safety management principles. The commenter asserted that such requirements would effectively address the low-probability, high-consequence events that management systems do not fully consider.

Response: The BSEE evaluated the OSHA, *Process safety management of highly hazardous chemicals,* 29 CFR 1910.119 requirements. The elements in the PSM requirements are very similar to those included in SEMS (*e.g.,* training, management of change, and auditing). However, BSEE determined that the SEMS approach is more appropriate because it was developed specifically for the offshore oil and gas industry and therefore addresses processes unique to OCS operations.

The term ''critical equipment'' is used in the API RP 75 (defined in Appendix D) and Subpart S. A SEMS program addresses all types of operations and equipment on a variety of OCS facilities, including low-probability, high-consequence events and high-probability, low-consequence events. The SEMS requirement that the operator identify the ''critical equipment'' on a facility and the requirement to conduct a hazards analysis are methods to prioritize hazards (low-probability, high-consequence events and high-probability, low-consequence events) and develop appropriate mitigation measures to address the identified hazards.

Goal Setting

Comment: Several commenters stated that BSEE should establish a broader, ''holistic'' regulatory strategy for offshore facilities that is based on setting goals. As part of the overall strategy to transition to a goal-setting regulatory culture, the commenters stated that SEMS should be structured as a goal-setting safety management regime. One commenter elaborated on this suggestion by adding that SEMS should be based on operator (not regulator) responsibility, risk management (not prescription), and regulatory oversight (not regulator command-and-control). This commenter also stated that BSEE should allow operators to establish audit programs, JSA criteria, employee input programs, stop work procedures, and facility management procedures that are best suited to their organization and culture. Also, the commenter stated that BSEE should encourage operators to follow practices that are best for their particular circumstances, and monitor the operator's performance to evaluate their success.

Response: The SEMS approach, consistent with API RP 75, integrates a variety of safety management initiatives that give the operator the flexibility to comply with regulatory requirements. Examples of similar provisions are: Subpart O performance-based training regulations; Subpart A, the use of alternate procedures or equipment at § 250.141; and the use of customizable field rules in Subparts D, E, and F. In § 250.141, BSEE allows an operator to propose the use of new operational procedures or equipment not already addressed in our regulations. These ''alternate'' procedures and technologies provide a mechanism for the industry to develop and use alternate procedures and technologies, with approval from BSEE as long as the proposed alternate procedures and technologies provide an equivalent of higher of safety and environmental protection on the OCS. Additionally, § 250.463 (field drilling), § 250.512 (field well-completion), and § 250.612 (field well-workover) requirements allow us to establish rules specific to a particular field that are different from what is required in the regulations if local geologic and engineering information show they are appropriate.

Overly Prescriptive

Comment: One commenter stated that many elements of the proposed rule

were overly prescriptive, and unnecessarily and inappropriately restricted options for managing OCS activities. The commenter also viewed the existing SEMS rule as overly prescriptive. The commenter stated that a major contributor in this regard was BSEE's substitution of the word ''shall'' for ''should'' regarding the incorporation of API RP 75 into Subpart S. Commenters urged BSEE to make the regulations less prescriptive by completely re-writing 30 CFR part 250, subpart S, and the means by which it has incorporated the provisions of API RP 75 into Subpart S.

Response: The BSEE agrees with this comment in part. Regarding the prescriptive nature of the regulations as they incorporate API RP 75, we have removed the ''should''/''shall'' language from § 250.1904. This language has also been removed from § 250.198(a)(3) under the recently published rule on Increased Safety Measures for Energy Development on the Outer Continental Shelf (77 FR 50856).

The overarching mechanism used by an operator to develop and implement its SEMS program provides avenues of flexibility, including the following:

1. The operator may apply the JSA to recurring events;
2. The operator has the freedom to select the individual with UWA; and
3. The operator can determine training frequency, training methodology, and the training vendor, except in specific cases where certain training requirements are specified in Section 7 of API RP 75.

The BSEE has removed prescriptive language related to training from proposed §§ 250.1911(c) and 250.1933(g). There is no need to prescribe each aspect of an operator's SEMS training program or how frequently an operator must conduct periodic training. The final regulatory text in § 250.1915 is sufficient to cover the detailed training requirements for an operator's SEMS programs. The introductory language establishes that all personnel must be trained to perform work safely. These changes allow operators to take responsibility for implementing their own training in accordance with the regulations.

The main element of prescription that was added to Subpart S was the requirement to conduct a JSA for all tasks addressed in a SEMS. As discussed in the preamble of the proposed rule, JSAs are not covered in API RP 75. Nevertheless, SEMS maintains performance flexibility as evidenced by the discretion granted to operators to develop their EPP and SWA programs. We also eliminated the requirement that personnel must be given cards with BSEE hotline number for reporting unsafe working conditions.

Suggested Improvements for BSEE

Comment: One commenter indicated that BSEE needs to make significant operational changes and increase oversight and inspection capabilities. The commenter also believes that BSEE should ensure a fundamental transformation in the offshore industry's safety culture.

Response: Since the *Deepwater Horizon* explosion and oil spill, BSEE has developed rulemakings to enhance safety and environmental protection and to increase BSEE oversight (*e.g.,* the final rule on Increased Safety Measures for Energy Development on the Outer Continental Shelf (77 FR 50856)). The BSEE is also currently developing other rulemakings to address items such as the design, manufacture, repair, testing, operational verification, and capabilities of blowout preventers; and production safety systems, lifecycle analysis, quality assurance, and safety device testing.

The BSEE understands the importance of improving the safety culture across the OCS. The BSEE's intent in implementing the SEMS program is the development and implementation of a safety culture within an organization, which is a step to enhancing a safety culture throughout the entire industry. It is BSEE's intent to use this rulemaking as a step to enhance safety culture throughout industry.

International Regulators

Comment: A few commenters suggested that BSEE should align itself better with its international peers. These commenters asserted that safety management is a regulatory approach, not an element of a prescriptive regulatory regime. They believe that implementing the SEMS program must be accompanied not with layers of new regulations and approvals, but with regulatory reform consistent with the international consensus. They would also like BSEE to explain how SEMS compares to the regulatory regimes of international regulators with established (*e.g.,* Norway, United Kingdom (UK), and/or the Netherlands) and emerging (*e.g.,* Australia) safety regulations.

Response: The BSEE actively participates in the International Regulators Forum and shares lessons learned among the Forum's member countries. The BSEE also participates in the Arctic Council's Protection of the Arctic Marine Environment (PAME) Working Group. The DOI Secretary is committed to the Arctic Council's initiatives, and BSEE supports the Secretary's commitment by contributing expertise at PAME meetings and conferences.

Regarding other international regulators, there are significant differences between BSEE's SEMS program and the use of management systems by other regulatory bodies across the globe. The legal, political, and operational environments vary from one country to another. Some of these differences include: the number of offshore facilities in one area as compared to another; the structure of the various operating companies (multinational, small, independent); and whether and how labor or trade unions are involved in the different areas. These and other distinctions make it difficult to directly compare OCS management systems (*i.e.,* SEMS) with those used in the United Kingdom (*i.e.,* Safety Case), Norway, Australia, and/or the Netherlands. All of these regulatory regimes have tailored the use of management systems to the specific local conditions prevalent in their respective areas.

Compliance Metrics

Comment: A commenter stated that BSEE has expressed a desire to have a risk-based inspection system and to ''develop metrics that demonstrate industry's degree of compliance with new regulatory requirements.'' Also, the commenter stated that the splitting of BOEMRE into BOEM and BSEE has created a departmentally mandated firewall between the Office of Offshore Regulatory Programs and the Economics Division (which is in BOEM), removing the technical and statistical expertise from the Office of Offshore Regulatory Programs in BSEE.

Response: We believe that BSEE possesses the necessary expertise to develop the appropriate metrics that will demonstrate industry's degree of compliance. We generate annual incident statistics from reports received from OCS operators in accordance with the Incident Reporting Rule (71 FR 19640, April 17, 2006) and publish this information on our Web site. We will determine industry's degree of compliance with the SEMS regulatory requirements by conducting, participating in, or directing audits of operators' SEMS programs. We are currently working with the Center for Offshore Safety (COS) workgroups on developing indicators to gauge industry OCS performance and would appreciate additional ideas related to metrics (*i.e.,* lagging or leading) from other stakeholders. The BSEE continues to

work with BOEM on functions that have interdependence.

Increased Financial Burden

Comment: A commenter stated that increased regulation and the resulting enforcement significantly underestimate the regulatory burden and energy costs to consumers. The commenter also stated that current standards and self-regulation by Gulf of Mexico operators remain satisfactory. The commenter asserted that government regulations will ultimately hinder innovations that increase safety and productivity.

Response: The BSEE disagrees with this comment. The SEMS program is a safety management system based on an industry standard that promotes innovation regarding operator safety. The commenter did not provide additional information to support the assertion that BSEE underestimated the regulatory burden or any increased costs. The Regulatory Impact Analysis assesses the costs of this rulemaking and provides further details. We consider this regulation critical to ensuring continuous safety improvements on the OCS.

Enhanced Drilling Safety

Comment: One commenter suggested that these SEMS revisions explicitly state that U.S. flagged vessels covered by a Document of Compliance with the International Safety Management (ISM) program be considered substantially equivalent to the SEMS requirements without any further documentation.

Response: The BSEE is aware of the differences in scope between the SEMS program and the requirements mandated within the ISM program. There is nothing in this rule preventing the operator from including ISM requirements in its SEMS program.

Section-by-Section Discussion of the Final Rule

The industry trade organizations (*e.g.,* Offshore Operators Committee, American Petroleum Institute (API), and International Association of Drilling Contractors (IADC)) and OCS operators submitted extensive lists of specific comments for most sections of the proposed rule. We responded to some of their comments in the General Comments section. The following addresses more specific comments not already discussed.

Definitions. (§ 250.105)

Section 250.105 now contains a definition of ''facility'' for Subpart S purposes.

Comment: A commenter wrote that there is no definition of ''facility'' in the existing § 250.105 that is applicable to Subpart S, nor is this term defined within Subpart S.

Response: The BSEE disagrees in part. The term ''facility'' was defined in § 250.1911, which stated how this term is used throughout Subpart S. However, BSEE agrees with the comment about § 250.105. Therefore, to eliminate any confusion over this term, BSEE removed the definition of facility from § 250.1911 and added it in the definition of facility under § 250.105.

Reports and Investigations of Possible Violations (§ 250.193 Includes Certain Language From Proposed § 250.1933)

The BSEE moved the language describing the process by which personnel may report unsafe working conditions from proposed § 250.1933 to § 250.193. This change consolidates the reporting process for any possible violation into one section. The BSEE retained the language regarding operator procedural requirements for unsafe working conditions in § 250.1933. The BSEE also changed the term ''apparent violation'' to ''possible violation'' throughout the section and in the title. Under the final rule, personnel only need to identify that a violation may have occurred; they are not required to know whether a specific legal requirement was actually violated in order to report unsafe conditions. However, a report should contain sufficient information to establish a reasonable basis for BSEE to determine whether a violation or other hazardous or unsafe working condition exists.

Documents Incorporated by Reference (§ 250.198)

The BSEE is incorporating three Center for Offshore Safety (COS) standards and one International Organization for Standardization (ISO) standard at § 250.198. These standards address requirements for accreditation bodies, qualifications for audit teams and auditors, requirements for auditing, and requirements for accreditation of audit service providers. The BSEE believes these standards will substantially improve the SEMS auditing process.

Must I have a SEMS program? (§ 250.1900)

The BSEE removed the deadline of November 15, 2011, for having a SEMS program that complies with Subpart S because that date has passed. However, removing the date does not excuse operators in existence before November 15, 2011, from compliance with the rule then in place. Removing the date simply removes reference in the regulatory text to a date that is now passed. The BSEE will take enforcement action against any operators that were operating before November 15, 2011, whose SEMS programs were not in compliance with Subpart S by November 15, 2011. Furthermore, as of that date, we expect all new operators to be in compliance with Subpart S from the first day of operation.

The BSEE is revising paragraph (a) to make clear that Subpart S takes precedence over any conflicting language in the documents incorporated by reference. Additionally, the BSEE removed paragraph (b) because it is redundant with § 250.1929.

What is the goal of my SEMS program? (§ 250.1901)

The BSEE received a comment concerning the operations that may be performed by a mobile offshore drilling unit (MODU) and whether or not decommissioning must be covered by a SEMS program. The BSEE agrees that this issue needs clarification, and has revised § 250.1901(a) accordingly. Decommissioning is encompassed within the meaning of *operation.* The SEMS program addresses facilities and all stages of OCS operations, from start to finish, which includes decommissioning. This requirement applies to all facilities, including MODUs when they are attached to the seabed.

What must I include in my SEMS program? (§ 250.1902)

The BSEE developed additional requirements for Subpart S in this rulemaking. The final rule revised this section to include references to the following new sections and requirements: SWA (§ 250.1930); UWA (§ 250.1931); EPP (§ 250.1932); and guidelines for reporting unsafe working conditions (§ 250.1933). These are additional requirements that must be included in an operator's SEMS program.

Definitions (§ 250.1903)

The BSEE added a list of acronyms and the following five new definitions: *accreditation body* (AB*), audit service provider* (ASP), *corrective action plan* (CAP), *personnel,* and *ultimate work authority* (UWA). The CAP definition was added to further increase the readability and clarity of the SEMS auditing requirements. The definition for *MODU* was removed from the final rule. The BSEE removed the definitions for *Management* and *Designated and Qualified Personnel (DQP).*

Comment: Several comments stated that the MODU definition should be

consistent with the USCG's MODU definition.

Response: The BSEE removed the definition of *MODU* from the final rule. The term *MODU* had been defined to mean a vessel capable of engaging in drilling, well workover, well completion, decommissioning, temporary and permanent abandonment, or well servicing operations for exploring or exploiting subsea oil, gas, or other mineral resources. The BSEE removed the definition of *MODU* because BSEE believes it is already clearly understood among operators that MODUs include vessels that are involved in other operations besides drilling.

Comment: Other comments stated that the definition of *Management* appears to be intended for the proposed new § 250.1932 and is not necessary as a definition in the regulations.

Response: The BSEE agrees with the comment and has removed the definition of *Management* from § 250.1903. Since BSEE removed the definition of *Management,* the EPP requirements under § 250.1932 were altered to reflect this change. Removal of this term allows the operator to decide who is considered management for the purposes of its SEMS program. The BSEE will hold the operator responsible for complying with its own determination of management as part of any SEMS audits conducted on the operator's program.

Comment: It was suggested that the definition of *Designated and qualified personnel* be removed.

Response: The BSEE agrees with this comment and made several changes to § 250.1902 to enhance the SEMS auditing requirements. The BSEE removed the definition of *Designated and qualified personnel* from § 250.1903 and all other sections within Subpart S. Operators are now required to have their SEMS program audited by an accredited ASP. The BSEE must approve the AB that accredits the ASP.

Comment: A question was asked if the definitions of *job* and *work* were required in an operator's SEMS program.

Response: The BSEE does not believe the terms *job* and *work* need to be defined for the purposes of Subpart S. These are terms commonly used by industry and BSEE does not feel there will be any confusion. However, an operator may define either or both of these terms in its SEMS program if it sees value in doing so.

Documents Incorporated by Reference (§ 250.1904 Current Section Title) Special Instructions (§ 250.1904 Final Rule Title)

The BSEE replaced the title and language of § 250.1904 because the existing language in § 250.1904 was redundant with § 250.198. The new title is Special Instructions. The new language clarifies the terminology used in the COS and the ISO documents incorporated by reference for purposes of these regulations and allows them to be applied across the OCS. For Subpart S purposes, references in the COS documents to *deepwater* means all water depths, and references to COS *member companies* means all operators. For Subpart S purposes, references in the ISO/IEC (International Electrotechnical Commission) document to *conformity assessment body (CAB)* means an ASP.

What hazards analysis criteria must my SEMS program meet? (§ 250.1911)

The BSEE now requires the operator to prepare, conduct, and approve JSAs for OCS activities identified or discussed in its SEMS program. The JSA is a tool used to identify risks to personnel associated with their job activities. The JSAs are also used to determine the appropriate risk mitigation measures.

The BSEE has added phrases related to environmental hazards and impacts to this section in order to ensure regulatory consistency throughout this section and Subpart S in general. The task level analysis should mirror that conducted at the facility level under § 250.1911(a)(1)(iv). This paragraph requires consideration of impacts to the human and marine environment. Therefore, BSEE added the phrases *environmental hazards* and *environmental impacts* to §§ 250.1911(b)(1)(ii) and (iii), respectively. These additions are consistent with the management of change requirement in § 250.1912(d)(2). The overall goal of SEMS under § 250.1901(a) requires operators to include impacts and environmental hazards in their SEMS programs.

The addition of these environmental references is also necessary in order to properly explain the context in which a single JSA may be used for recurring activities. The person in charge must consider several factors in making this determination, including changes in personnel, procedures, equipment, and/or environmental conditions associated with the activity. In accordance with § 250.1915, the operator must provide training for all personnel on how to recognize and identify hazards and how to develop and implement JSAs prior to performing a job on the facility.

The BSEE removed the phrase "* * * that are regulated under BSEE jurisdiction * * *" from paragraphs (b) and (c) in response to comments received on this subject and as further discussed in the General Comments section.

Comments: Several comments were received concerning JSA training requirements, as well as questions regarding who has the authority to approve and sign a JSA. Commenters also stated that the entire JSA process is too demanding and onerous. Commenters were primarily concerned about the proposed rule's clarity in relation to JSAs. They believe that the JSA should not include all personnel affected by the activity being conducted.

Response: The BSEE believes the proposed modifications to the JSA requirement will lead to safer OCS operations. The component of the training focused on JSA development and implementation should improve an operator's and contractor's ability to perform an activity in a safe manner. In addition, training will provide personnel a better understanding of how a SEMS program addresses particular hazards. The final rule does require the JSA to include all personnel involved with the job activity being conducted. The personnel performing the job must be aware of the hazards and sign the JSA. The immediate supervisor of the crew actually performing the job needs to conduct the JSA, sign the JSA, and make sure all personnel participating in the job sign the JSA. The individual designated as being in charge of the facility by the operator must approve and sign all JSAs. Having dual levels of involvement/approval in the JSA process provides an extra level of safety.

Providing signatures is an indication by the individuals signing the JSA that they are aware of the hazards and will adhere to the recommended preventions and mitigations while performing and/or supervising the job. This requirement will help minimize the possibility of safety or environmental issues. Requiring signatures from all parties is appropriate. The BSEE has found that not performing a JSA, conducting an incomplete JSA, or not having all parties involved in the task participate in the JSA process has contributed to accidents or Incidents of Noncompliance (INCs). The BSEE believes that requiring signatures on the JSA will ensure a better understanding of the proper way to perform operations and will better ensure that all personnel involved in the job understand the risks, procedures,

and expectations of the task at hand before initiating work.

The BSEE has accepted the commenter's recommendation to remove the phrase *affected by* from the JSA section of the final rule.

Comment: One commenter suggested that electronic signatures should be accepted for JSAs.

Response: The BSEE agrees. An electronic signature on the JSA is an acceptable alternative to a written signature, as long as the operator's SEMS program states that electronic signatures are acceptable.

Comment: A commenter recommended revising the proposed § 250.1911(b) to read as follows: ''The JSA must include all personnel involved with the job activity.''

Response: The BSEE agrees with this comment and has made this revision.

What criteria must be documented in my SEMS program for safe work practices and contractor selection? (§ 250.1914)

To ensure consistent language throughout Subpart S, BSEE updated the language in this section to replace references to *operator* and *lessee* with *you* or *your*.

What training criteria must be in my SEMS program? (§ 250.1915)

The BSEE now requires a SEMS program to establish and implement a training program so that all personnel are trained in accordance with their duties and responsibilities to work safely and are aware of environmental impacts. Training must address operating procedures (§ 250.1913), safe work practices (§ 250.1914), emergency response and control measures (§ 250.1918), SWA (§ 250.1930), UWA (§ 250.1931), EPP (§ 250.1932), and reporting unsafe working conditions (§ 250.1933); how to recognize and identify hazards (§ 250.1911); and how to construct and implement JSAs (§ 250.1911).

Comment: One commenter stated that to reduce the ambiguity of the present and proposed provisions of Subpart S regulations, BSEE should articulate what training in a MODU owner's SEMS program is required for various rig activities and systems.

Response: As stated in § 250.1915, an operator's SEMS program must establish and implement a training program so that all personnel who perform activities on the OCS, including personnel on a MODU performing activities on the OCS, are trained in accordance with their duties to work safely and are aware of potential environmental impacts. An SWA training program will be required on a MODU if these workers are involved with a task or job. The required training imposed on the operator must be in accordance with § 250.1915 and API RP 75.

What are the auditing requirements for my SEMS program? (§ 250.1920)

The BSEE's current regulations require operators to conduct a comprehensive SEMS audit within a 3-year cycle. This final rule clarifies that the cycle begins on the start date of each audit (including the initial implementation audit) and ends on the start date of the next audit. An operator's SEMS program must be audited by an accredited ASP according to the requirements of Subpart S. Operators must include the ASP's qualifications in their audit plans. Operators must also provide us with a copy of the audit report and their CAP. We extended the deadline for submitting audit reports and CAPs from within 30 days of the audit completion date to within 60 days of the audit completion date in this final rule.

Comment: One commenter stated that the rule should retain the option to allow designated and qualified personnel to lead an audit. The commenter stated that there are not enough skilled and knowledgeable independent third party (I3P) auditors available to conduct these audits. In addition, the commenter stated that using designated and qualified personnel ensures that operator audits are conducted by personnel with the highest knowledge of the operator's SEMS program.

Response: The BSEE disagrees in part with this comment. The option for the operator to use designated and qualified operator personnel to lead an audit was removed in this final rule from Subpart S and replaced with an accredited ASP. Consistent audits performed by well trained and experienced auditors are critical to ensuring that SEMS programs are successfully implemented and maintained on the OCS. As a result, we are adopting industry best practices related to SEMS audits and auditor qualifications. Industry is already voluntarily adopting these practices in many deepwater operations. We believe that the application of these requirements to all OCS operations will result in more robust and consistent SEMS audits.

To ensure that a sufficient pool of auditors is available, the compliance date for this audit requirement is January 1, 2015, over 2 years from the date this rule will become effective. This compliance date gives the industry sufficient time to develop an adequate number of qualified SEMS auditors.

What qualifications must the ASP meet? (§ 250.1921)

The BSEE added this section to include the minimum qualifications that the ASP must meet. These qualifications were developed with consideration of guidelines issued by the COS. The ASP must be accredited by a BSEE-approved AB.

Comment: Some commenters were concerned that the exclusion of those individuals already involved in program development will lead to the use of less qualified individuals who may not be equipped with the knowledge to properly evaluate the effectiveness of the SEMS program. The commenters believe that imposing these minimum qualifications could greatly reduce the potential for positive safety and environmental gains expected from full SEMS implementation.

Response: The BSEE agrees with this comment in part and altered the final rule to mitigate this concern. Operators are now required to audit their SEMS program by using audit teams from an accredited ASP. The prohibition against qualified operator personnel participating in the audit was removed. Instead, the rule now requires that only the audit team lead must be an ASP employee, representative, or agent, and must not have any affiliation with the operator. The remaining team members may either be operator personnel or that of the ASP. This option gives the operator the flexibility to utilize in-house expertise on the audit team. This rule adopts the latest industry standards related to auditor qualifications.

What qualifications must an AB meet? (§ 250.1922)

The BSEE has eliminated the I3P process in this final rule and added this section to implement a new process to handle approving auditor teams. The BSEE will now approve ABs which will accredit ASPs that have the necessary expertise and training to perform SEMS audits. The AB will be required to satisfy the requirements of ISO/IEC 17011. The ISO/IEC 17011 standard provides international guidelines for ABs.

Comment: Several commenters support the concept of utilizing I3P auditors to assess SEMS compliance. One commenter stated that it is inconsistent with safety management principles for BSEE to approve I3Ps. Commenters believe auditors should be approved through the API COS program.

Response: The BSEE agrees with this comment. The I3Ps were replaced by

ASPs. The BSEE will not review and approve audit teams. The BSEE will rely on ABs such as the COS to determine which ASPs meet the necessary qualifications and experience to perform SEMS audits. The BSEE will approve and evaluate ABs responsible for ASP certification. The BSEE has added new sections to the final rule to address the role of an ASP (§ 250.1921) and an AB (§ 250.1922). The rule also defines the functions and standards of the ABs regarding the accreditation process. Operators will be able to choose from a pool of accredited ASPs. Implementing the AB and ASP structure will ensure consistent measurement of SEMS performance and resolution of safety deficiencies within companies and across industry.

[Reserved] (§ 250.1923)

How will BSEE determine if my SEMS program is effective? (§ 250.1924)

The BSEE requires the operator to conduct SEMS audits using an accredited ASP. The BSEE, or its authorized representative, may evaluate any and all aspects of your SEMS program as outlined in Subpart S. These evaluations or visits may be random or may be based upon operator or contractor performance.

May BSEE direct me to conduct additional audits? (§ 250.1925)

This section explains the circumstances under which BSEE may direct operators to conduct an audit and the timeframe for submitting audit reports for BSEE-directed audits. The BSEE updated this section to replace references to I3P with ASP and to ensure consistency with the new language and requirements of §§ 250.1920 and 250.1921. Additionally, BSEE removed existing § 250.1925(b), stating that audit findings may be used in enforcement actions, because it was redundant (also expressed in § 250.1927). Removing paragraph (b) does not affect BSEE's ability to use audit findings to enforce regulations.

[Reserved] § 250.1926

This section was replaced with § 250.1921.

What are my recordkeeping and documentation requirements? (§ 250.1928)

For documenting JSAs and SWA procedures, records must be kept onsite for 30 days. In the case of a MODU, records must be kept onsite for 30 days or until the operator releases the MODU, whichever comes first. The BSEE has removed from this section the requirements for training on SWA policies and a review of SWA procedures as a part of all meetings where the primary topic applies to facility safety, although the SWA procedures still must be reviewed at those meetings under § 250.1930(e).

Comment: One commenter stated that not all facilities have the capability to maintain records. Therefore, the commenter suggested that the language should allow records to be maintained at the nearest field office where such records are maintained.

Response: In existing § 250.1928(a), all SEMS program documents must be maintained at an onshore location. However, there are some records that BSEE believes are important to also maintain on the actual facility where the task, operation, or job has been performed. These records include those associated with SWA and JSA, as specified in § 250.1928(b) and (f) of the final rule. If a facility does not have the capability to maintain onsite records for the period of time specified in the rule, then that facility needs to be modified. Records can be maintained electronically or as paper.

Comment: A commenter stated that documentation cannot be expected to be retained on a MODU if the operator releases the MODU prior to the 30-day required record-retention time frame.

Response: The BSEE agrees. The BSEE modified the regulatory text to state that in the case of a MODU, records must be kept onsite for 30 days or until the operator releases the MODU, whichever comes first.

What must be included in my SEMS program for SWA? (§ 250.1930)

This final rule will require operators to create and implement a SWA program. This program will ensure that all personnel are given the responsibility and authority to stop work when they witness an activity that creates an imminent risk or danger to the health or safety of an individual, to the public, or to the environment. The SWA will include authority to stop the specific task(s) or activity that poses an imminent risk or danger as defined in § 250.1930(a).

The rule provides further that individuals who receive notification to stop work must comply with the direction immediately. In supporting the safe execution of work and to promote a culture of safety at work, all personnel should have the responsibility and authority, without fear of reprisal, to stop work or decline to perform an assigned task when an immediate risk or danger exists. Personnel exercising the SWA should have discussions with co-workers, supervisors, and/or safety representatives to attempt to resolve any safety issues that are causing the imminent danger or risk. When a work stoppage occurs, the final rule provides that the person in charge of the conducted activity is responsible for ensuring the work is stopped in an orderly and safe manner. The final rule further provides that work may be resumed when the individual on the facility with UWA determines that the imminent danger or risk does not exist or no longer exists.

The BSEE now requires the operator to conduct training on their SWA procedures as part of orientations for all new personnel who perform activities on the OCS. Additionally, the SWA procedures must be reviewed as part of all safety-focused meetings related to facilities subject to SEMS.

Comment: Commenters stated that the SWA program should remain voluntary rather than mandatory. In past OCS accidents, the SWA program did not function as designed because personnel hesitated to implement this provision due to fear of reprisal.

Response: The BSEE believes that a mandatory program is necessary to promote safety on the OCS and ensure that all personnel are aware of their responsibility to implement the program.

Comment: A commenter stated that the individual with UWA on a facility may not always be the appropriate party to authorize the startup of activities following a work stoppage, and that the immediate task supervisor would be a more appropriate individual to make the decision.

Response: The BSEE disagrees. The individual with the UWA is responsible for overall facility safety and operations. Therefore, this individual is best qualified to make the decision regarding when a crew should return to work.

Comment: There was a recommendation to remove the word *drill* at the end of proposed subsection (d) and make JSA plural.

Response: The BSEE agrees and made the suggested corrections.

Comment: A commenter stated that the term *safety meetings* is not defined and potentially includes non-safety topics when a brief introductory item related to safety is provided as a matter of course. The commenter suggested alternative language to this proposed subsection to read as follows: ''* * * review of the SWA policy must be completed as part of all meetings relating to facilities subject to SEMS for which safety is the primary topic of the meeting.''

The commenter also proposed that the references in this section to *SWA policy and program* and *SWA policy* should be replaced with *SWA procedures,* which is the term used in § 250.1930(a).

Response: The BSEE agrees with the comments. The BSEE has always intended for this section to apply to meetings where safety is the primary subject. It is not intended that SEMS be included in meetings where safety is addressed as a passing or indirect reference. The regulatory text has been changed in § 250.1930(e) to read as follows:

''You must conduct training on your SWA procedures as part of orientations for all new personnel who perform activities on the OCS. Additionally, the SWA procedures must be reviewed during meetings focusing on safety on facilities subject to this subpart.''

Comment: Several commenters stated that most operations present some level of danger when they are being conducted. However, the commenters asserted that the risk can be managed and mitigated through the application of barriers or controls. The commenters stated that the draft text should therefore be qualified to show that SWA is applicable when a threat or danger is outside of the ordinary. Commenters also recommended changing the wording of SWA to not only address imminent risk or danger, but risk or danger that is also significant. The commenters recommend changing the wording to ''*and witness any activity that creates an imminent and significant risk or danger.''*

Response: The BSEE agrees in part. Most OCS operations present a level of danger; however, the quantification of risk as *significant* is difficult. Consistent with the philosophy used in the development of the SEMS rule, BSEE made the determination that the operator has flexibility to determine which activities and associated risks need to be addressed in a SWA program; therefore, BSEE did not adopt this proposed change.

What must be included in my SEMS program for UWA? (§ 250.1931)

The final rule now requires that an operator's SEMS program specify who has the UWA on the operator's facilities. This requirement could be met, for instance, by posting a notice in an easily accessible public location. The individual with UWA will be the individual on the facility with the final responsibility for making decisions. The individual with UWA has a key role in assuring that the operator's SEMS program is implemented in a manner that addresses personnel safety and environmental protection.

Under the final rule, the operator's SEMS program must identify and designate the individual with the UWA on the facility. Only a single individual will have UWA at any given time, so operators must take into consideration all applicable USCG regulations that deal with designating a *person in charge* (in accordance with USCG regulations) of a MODU or a floating facility on the OCS.

Section 250.1931(c) in the proposed rule was removed from the final rule. Since *facility* is now defined to include fixed and floating facilities, there was no need to explicitly state that the SEMS program applies to these facilities. The final rule requires that an operator implements all provisions of its SEMS program at all times on all facilities as defined in the final rule.

Comment: One commenter stated that for unmanned facilities where personnel may be working on a daily basis and not spending the night, the individual with UWA may not be located on that facility but located somewhere else (either offshore or onshore). To eliminate this confusion, the commenter recommended removing the requirement for the individual with UWA to be located on the facility.

Response: The BSEE disagrees. All facilities need to have an individual identified by the operator located onsite as the one with UWA. This requirement applies to *unmanned facilities,* as well as when a crew is performing work on those facilities.

Comment: Several commenters stated that the proposed Subpart S regulation fails to address UWA in situations where multiple facilities are attached (*e.g.,* a jack-up MODU performing drilling, well-workover, well-completion, or well-servicing operations over a fixed platform) or in close proximity to each other when conducting OCS operations.

Response: The BSEE agrees. The intent of the regulation is to assure that the individual with UWA is identified in an operator's SEMS program for all facilities. Recognizing that compliance with this requirement is complex when facilities are attached or in close proximity to one another, this final rule clarifies that the operator needs to identify an individual with overall UWA for all the facilities involved in a common operation. The BSEE added the following sentence at the end of § 250.1931(a), ''In the event that multiple facilities, including a MODU, are attached and working together or in close proximity to one another to perform an OCS operation, your SEMS program must identify the individual with the UWA over the entire operation, including all facilities.''

Comment: One commenter stated that the bridging arrangements contemplated by the proposed API/IADC Technical Bulletin (TB) 97, *Well Construction Interface Document,* could be used in a flexible manner so as to assure the identification of the individual or position having UWA, both for stand-alone and for combined operations.

Response: The BSEE will review the API/IADC TB 97 for possible incorporation by reference into our operating regulations when it is complete. For operations conducted from a MODU, TB 97 could present a viable alternative to meet the intent of the UWA regulation if this document is identified by an operator as being part of its SEMS program.

Comment: Several commenters stated that rather than identify an individual person with UWA, identifying the position with UWA would be more appropriate. This specification would alleviate possible confusion associated with crew changes/rotations for the individual designated as having UWA. All personnel would know that a particular position retains the UWA rather than a specific individual.

Response: The final rule states that the operator must identify the individual or position with UWA in its SEMS program. The operator has discretion to decide to identify an individual or a position with the UWA.

Comment: One commenter suggested relocating the language in § 250.1931(c) to a different section of Subpart S.

Response: This section does not apply to UWA and was removed from the rule because it is already covered in § 250.1902. Because of this change, BSEE redesignated § 250.1931(d) to now be § 250.1931(c).

What are my EPP requirements? (§ 250.1932)

This rule now requires operators to develop and implement an EPP. Under this rule, an operator who performs regulated activities on the OCS will be required to consult with its employees regarding the development, implementation, and modification of its SEMS program. The operator will also have to develop a written plan of action regarding how appropriate onshore and offshore employees will participate in the SEMS program development and implementation. The operator will have to provide its personnel access to relevant sections of the SEMS program.

Comment: Several commenters stated that this section is out of sequence with the overall compliance timeline of the

SEMS program. It requires employee participation in the plan with specific requirements for employee consultation and a written plan, among other things. The commenters noted that this new section will be effective at some future date that was not specified in the proposal. Therefore, the commenters asserted, it will be difficult to comply with this employee participation provision since the program elements will already be developed and implemented before the new EPP requirement is finalized and made effective. The commenters stated that industry believes that it could include affected employees in future SEMS modifications. Moreover, the commenters stated that appropriate employee participation will be evident through the audit of an operator's SEMS.

Response: The BSEE disagrees. The SEMS is a dynamic program. Requiring the operator to have an EPP will ensure that all employees understand and are involved in updating the SEMS program on an ongoing basis. The EPP adds value to the overall safety of OCS operations because this plan provides employees a stake in the development and implementation of an operator's SEMS program. This program engages employees in the field and in the office, bridging a significant gap between those actually performing OCS operations and those planning, managing, and/or monitoring these operations in an onshore office. The EPP requirements provide the operator with a significant amount of flexibility to tailor this plan to its specific needs. The final rule grants operators one year after the effective date to modify their recordkeeping policies to capture EPP information.

Comment: One commenter stated that BSEE should require operators to fund worker safety expert(s) to participate in SEMS program development and implementation. The commenter stated that such experts should be selected by the workers, ideally by the applicable labor union.

Response: Operators have complete discretion to hire outside experts, including those affiliated with labor unions, to assist in developing and/or implementing their SEMS program.

Comment: Several commenters suggested that BSEE revise this section so that *you* replaces *management* and *your* replaces *their.*

Response: The BSEE disagrees. These regulations require management to make the EPP available during an audit; either a BSEE-conducted audit or an ASP audit. The BSEE believes that management is the most appropriate party to be responsible for this duty. If the term *management* was replaced with the term *''you''* it would allow management to avoid this responsibility.

However, BSEE agrees with the commenter's concern about who *management* is. As a result, BSEE has removed the definition of *Management* from § 250.1903. Removing this definition allows the operator to decide who is considered *management* for the purposes of its EPP. The BSEE will hold the operator responsible to comply with its own determination of who *management* is as part of any SEMS audits conducted on its program.

Comment: One commenter stated that an EPP is written into various sections of their overall SEMS. The commenter stated that the best way to prove that employees are participating in the SEMS program is through the audit process, as is already provided under existing rules. The commenter suggested that paragraph (d) be deleted.

Response: The BSEE agrees in part. The BSEE has deleted paragraph (d) because it was redundant with § 250.1924(b). However, per § 250.1924(b), BSEE still reserves the right to request a copy of the operator's SEMS program, which could include the EPP element. The BSEE may request these documents regardless of whether BSEE conducts an audit.

Comment: One commenter stated that an EPP is necessary. However, the commenter stated, ''it is the responsibility of the employer to develop the SEMS for the operations to be conducted by his or her employees with their participation; this program must then be deemed acceptable by the entity controlling the work site in a manner that can be coordinated with other operations. A general consultation by all 'management' (as defined in the regulations) is not needed, nor must it involve all 'employees' at the work site.''

Response: The BSEE disagrees. While an operator's management is tasked to include appropriate employees in the development and implementation of a SEMS, management must consult with all employees, including both the operator's office employees and employees working on offshore facilities.

What procedures must be included for reporting unsafe working conditions? (§ 250.1933—Certain language in § 250.1933 was moved to § 250.193 in the Final Rule)

To address redundancies between the proposed language of this section and § 250.193, certain requirements in the proposed rule were merged with § 250.193. All personnel are permitted, under § 250.193, to report to BSEE any hazardous or unsafe working conditions and any possible violations of an order, regulation, or any other provision of Federal law relating to offshore safety.

Section 250.1933 of the final rule requires the operator to develop procedures for reporting unsafe working conditions. These procedures must take into account the existing USCG unsafe working conditions reporting requirements currently found at 33 CFR 142.7 and 46 CFR 109.419.

Comment: Several commenters suggested adding a requirement to the proposed language for personnel to first notify the operator of unsafe conditions so that such conditions can be addressed and remedied immediately.

Response: The BSEE agrees with the comment but sees no need to revise the regulation. There is nothing in this requirement that prevents personnel from first notifying the operator of an unsafe working condition before they notify BSEE, regardless of whether the unsafe condition poses an imminent risk or danger. If personnel are conducting an activity and believe the activity poses an imminent risk or danger, they have the authority to stop work under § 250.1930. Once SWA is activated, management on the facility will be aware of the unsafe condition.

Comment: Several commenters objected to the posting of a notice at each work location explaining personnel rights and contact information. These commenters prefer to post this information on their companies' Web site. They believe that posting the information on their Web sites will ensure that the information is readily accessible at all times from any location. They felt that the requirement to provide a card containing BSEE's telephone number for information and reporting of unsafe activities would not accomplish the intended purpose since these cards could be easily lost or misplaced. They believe the distribution of cards will also be very burdensome given the level of activity in the OCS and the constant changing of personnel. The commenters did not object to initial briefings or annual reminders regarding the reporting opportunity and will incorporate this into their current training requirements for personnel.

Response: The BSEE disagrees in part. The BSEE requires the posting of notices, convenient and understandable for workers, so that when personnel are working in a potentially unsafe environment, they have access to the information necessary to call or go online to notify BSEE anonymously of

questionable/unsafe activity. There is nothing in this requirement that prohibits an operator from developing a provision in its SEMS program that states this information must be posted on an operator's Web site in addition to posting a notice at the work site that contains the reporting information contained in § 250.193.

We agree with the comment concerning the distribution of cards. We have removed the requirement for personnel to carry an unsafe working condition notification card. Instead, a new BSEE Toll-free Safety Hotline number and reporting Web site were established and are listed in this regulation under § 250.193.

Comment: One commenter stated that the proposed language in this section will apply to ''contractors providing domestic services to the lessee or other contractors, including domestic services include [*sic*] janitorial work, food and beverage service, laundry service, housekeeping, and similar activities * * *'' The commenter stated that the proposed language appears to be in conflict with existing § 250.1914(a), which excludes ''contractors providing domestic services to the lessee or other contractors'' from the definition of *contractors.*

Response: The BSEE disagrees. Section 250.193 allows all personnel, including contractors providing domestic services, to anonymously report to BSEE a possible violation of any order, standard, or regulation. The BSEE believes that the reporting requirement should include not only the contractors covered in § 250.1914(a), but all contractors on a facility, including a MODU, since individuals involved with any level of responsibility, including housekeeping and janitorial duties, can witness an unsafe act.

Comment: One commenter said that the training language in the proposed § 250.1933 states that follow-up training must be provided ''not less than once every 12 months thereafter.'' The proposed language of this subsection does not allow for a precise determination of the date by which follow-up training must be provided. The commenter asked whether *12 months* means 365 days, or does it mean that the follow-up training must be conducted during the same month that the initial training was conducted, or either? Several commenters stated that the time allowed for initial training (within 30 days of employment) was inadequate and it should be increased.

Response: The BSEE believes the existing training requirements in § 250.1915 are adequate. Therefore, the training frequency requirements in the proposed § 250.1933(g) have been removed from the final rule.

Comment: One commenter stated that the proposed language of § 250.1933(g) and (h) only applies to *employees* and not to *contractors.* It is the commenter's understanding that the intent is to limit the applicability of these proposed subsections to operator employees.

Response: The BSEE disagrees in part. Proposed § 250.1933(g) and (h) were removed from the final rule. However, BSEE maintains its position that training and safety requirements apply to all personnel as stated in § 250.1915. The definition of *personnel* in § 250.1903 includes contractors.

Comment: One commenter stated that this portion of the rule should be deleted since it is similar to the existing § 250.193.

Response: The BSEE agrees in part. The BSEE agrees that some parts of this section were redundant with § 250.193 and moved the relevant language to § 250.193.

Comment: One commenter stated that BSEE should clarify whether the reporting hotline is *toll-free.* If not, then BSEE should say so and state that it is going to make provisions for assuming any usage charges associated with calls from offshore locations to the numbers provided in the regulations.

Response: The BSEE disagrees. The final rule uses the term *toll-free;* its common meaning is that there are no long-distance fees charged for calling the hotline. Since the area code for the hotline is not a traditional *1–800* prefix, *toll-free* must be retained in order to ensure that personnel who wish to call in a report know that the hotline will not charge long-distance fees. However, users may still be responsible to their own communication service provider for applicable charges.

Comment: One commenter stated that BSEE should issue a supplemental notice of proposed rulemaking regarding the provisions of the proposed § 250.1933(e) to indicate that information reported over the hotline may be shared with officials of other agencies having jurisdiction, particularly if the report alleges criminal activity.

Response: The BSEE disagrees in part. A supplemental notice of proposed rulemaking is not necessary to resolve this concern. This language in the final rule has been moved to § 250.193. When a possible violation is reported, BSEE will investigate the matter and take appropriate action, which could include referral to other agencies.

Procedural Matters

Regulatory Planning and Review (Executive Orders (E.O.) 12866 and 13563)

This final rule is a significant rule as determined by the Office of Management and Budget (OMB) and is subject to review under E.O. 12866.

(1) This final rule will not have an annual effect of $100 million or more on the economy.

(2) It will not adversely affect in a material way the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities.

(3) This final rule will not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency.

(4) This final rule will not alter the budgetary effects of entitlements, grants, user fees, or loan programs or the rights or obligations of their recipients.

(5) This final rule might raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in E.O. 12866.

The E.O. 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the Nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The E.O. directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. The E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements.

Executive Order 13563 requires each agency to account for ''among other things, and to the extent practicable, the costs of cumulative regulations.'' The BSEE is using the Paperwork Reduction Act (PRA) Burden Table for Subpart S to estimate the cumulative cost of SEMS regulations. Due to this rulemaking, BSEE estimates a program increase of 186,629 burden hours imposed on private sector operators and a non-hour cost burden of $1,250,000. The total PRA hour burden inventory for the SEMS program required in 30 CFR 250 subpart S is estimated to be 651,728 hours inclusive of this rulemaking. The total non-hour burden is estimated to be $1,250,000 for the cost of paying

independent parties to audit SEMS implementation.

The full annual E.O. 13563 analysis costs of the SEMS requirements in Subpart S (this rulemaking and existing requirements) is summarized in the following Table.

E.O. 13563 SUMMARY COST

	Burden hours	Est. annual cost
PRA @ $86/hr.	651,728	$56,048,608
Non-Hour Cost Burden		$ 1,250,000
TOTAL:		$57,298,608

The BSEE has prepared an RIA for this rulemaking. The full analysis can be found on the Federal eRulemaking Portal: *www.regulations.gov.* In the entry titled *Enter Keyword or ID,* enter BSEE–2012–0011 then click search. Follow the instructions to view the RIA and submit public comments for this rulemaking.

The BSEE estimates the average annual cost of complying with this rulemaking is approximately $17 million, spread across all OCS oil and gas operators with active operations. The benefits of the SEMS provisions in this rulemaking will come from enhanced safety for offshore workers and greater protection of the marine environment. These benefits will be realized through additional employee participation in safety procedures, training programs, notification obligations as well as strengthened safety and SEMS auditing procedures.

The protection of human life and the environment are the top priorities and objectives of this rule. It is difficult to quantify the benefits of lives saved and risks avoided due to this regulation. However, implementing these requirements will further the goal of avoiding accidents that may result in injuries, fatalities or serious environmental damage.

The compliance cost for managing a comprehensive SEMS program is estimated to be very minor compared to the costs associated with major accidents. For example, in 1987, prior to industry's development of a safety management template for offshore operations, the Mississippi Canyon 311, A (Bourbon), platform in the Gulf of Mexico was tilted to one side by an extensive underground blowout. The cost associated with this incident alone was $274,000,000. In 1989, a fire associated with a pipeline repair killed 7 people and destroyed a major production facility. The 2010 *Deepwater Horizon* explosion and oil spill killed 11 people, destroyed the drilling rig, and caused billions of dollars in damages. A SEMS plan will implement procedures and evaluations that may prevent or mitigate the adverse consequences of these types of events. The BSEE concludes that these additional requirements will further enhance the existing safety management program on OCS facilities.

Regulatory Flexibility Act: Final Regulatory Flexibility Analysis

The BSEE has prepared a Final Regulatory Flexibility Analysis (FRFA) in conjunction with this final rule.

The FRFA for this final rule is available as part of the RIA. The FRFA can be found on the Federal eRulemaking Portal: *www.regulations.gov.* In the entry titled *Enter Keyword or ID,* enter BSEE–2012–0011 then click search. Follow the instructions to view the RIA and FRFA, and submit public comments for this rulemaking.

The changes in the final rule will affect lessees and operators of leases and pipeline right-of-way holders on the OCS. This group could include about 130 active Federal oil and gas lessees. Small lessees that operate under this rule fall under the Small Business Administration's North American Industry Classification System (NAICS) codes 211111, Crude Petroleum and Natural Gas Extraction, and 213111, Drilling Oil and Gas Wells. For these NAICS code classifications, a small company is one with fewer than 500 employees. Based on these criteria, an estimated 65 percent of these companies are considered small. This final rule, therefore, will affect a substantial number of small entities.

Small entities are represented in all activity levels of OCS operations (high, moderate, and low based on the number of offshore complexes the entity operates). Small companies will bear approximately 43 percent of the costs of this final rulemaking. While 43 percent is greater than small companies' percentage share of OCS leases, small companies hold 45 percent of leases in the shallow water depths where most production facilities are located (98 percent of active platforms are in shallow water).

The operating risk for small companies to incur safety or environmental accidents is not lower than it is for larger-sized companies. Offshore operations are highly technical and can be hazardous. The risk level along with the adverse consequences in the event of incidents is the same regardless of the operator's size. The BSEE evaluated a number of alternatives based on the size of an operator including those provided through comments but was unable to identify provisions that will impose lesser requirements on some operators and still achieve the same safety objectives.

The Small Business and Agriculture Regulatory Enforcement Ombudsman and 10 Regional Fairness Boards were established to receive comments from small businesses about Federal agency enforcement actions. The Ombudsman will annually evaluate the enforcement activities and rate each agency's responsiveness to small business. If you wish to comment on the actions of BSEE, call 1–888–734–3247. You may comment to the Small Business Administration without fear of retaliation. Allegations of discrimination/retaliation filed with the Small Business Administration will be investigated for appropriate action.

Small Business Regulatory Enforcement Fairness Act

The final rule is not a major rule under the Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 801 *et seq.*). This final rule:

a. Will not have an annual effect on the economy of $100 million or more.

b. Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.

c. Will not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

The requirements will apply to all entities operating on the OCS.

Unfunded Mandates Reform Act of 1995

This final rule will not impose an unfunded mandate on State, local, or tribal governments or the private sector of more than $100 million per year. This final rule will not have a significant or unique effect on State, local, or tribal governments or the private sector. A statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*) is not required.

Takings Implication Assessment (E.O. 12630)

Under the criteria in E.O. 12630, this final rule does not have significant takings implications. The final rule is not a governmental action capable of interference with constitutionally protected property rights. A Takings Implication Assessment is not required.

Federalism (E.O. 13132)

Under the criteria in E.O. 13132, this final rule does not have federalism implications. This final rule will not substantially and directly affect the relationship between the Federal and State governments. To the extent that State and local governments have a role in OCS activities, this final rule will not affect that role. A Federalism Assessment is not required.

Civil Justice Reform (E.O. 12988)

This rule complies with the requirements of E.O. 12988. Specifically, this rule:

(a) Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation; and

(b) Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

Consultation With Indian Tribes (E.O. 13175)

Under the criteria in E.O. 13175, we have evaluated this final rule and determined that it has no substantial effects on federally recognized Indian tribes.

Paperwork Reduction Act (PRA) of 1995

This rule contains a collection of information that was submitted to OMB for review and approval under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The title of the information collection (IC) for this rule is 30 CFR Part 250, Subpart S, *Safety and Environmental Management Systems for Outer Continental Shelf Oil, Gas, and Sulphur Operations.* The OMB approved the collection under Control Number 1014–0017, expiration 3/31/2016, 651,728 hours, $1,250,000 non-hour cost burdens. Respondents primarily are Federal OCS oil, gas, and sulphur lessees and/or operators or other independent third parties. The frequency of response varies, but is primarily annual. Responses to this IC are mandatory.

The BSEE will protect proprietary information according to the Freedom of Information Act (5 U.S.C. 522) and its implementing regulations (43 CFR part 2), and 30 CFR 250.197, *Data and information to be made available to the public or for limited inspection* and 30 CFR part 252, OCS *Oil and Gas Information Program.* The BSEE will use the information to evaluate the effect of industry's continued improvement of OCS safety and environmental management and its compliance with the regulations. It should be noted that while this rulemaking adds additional burden hours to industry, the vast majority of these hours stem from expanding their current SEMS program, along with documenting and recordkeeping relative to these expanded requirements, and to address issues raised in testimony, hearings, and reports being released about the *Deepwater Horizon* explosion and oil spill.

As stated in the preamble, BSEE received 35 sets of comments from individual entities (companies, industry organizations, or private citizens). In response to the comments, we made adjustments to both hour and non-hour cost burdens from the burdens published in the preamble of the proposed rule. The changes and reasons for making them are as follows:

—§§ 250.1900–250.1933 Operator Activity: Changes from the proposed to final rule incorporate refresher training requirements to coincide with audits, once every 3 years. These changes result in the following burden increases:
  (1) High Activity operator (+10,504 hours).
  (2) Moderate Activity operator (+8,405 hours).
  (3) Low Activity operator (+2,128 hours).

—§ 250.1911(b)—Expanded the requirement to include additional signatures but we deem that the current and proposed hour burden is sufficient to adequately cover the requirement.

—§ 250.1922—Added a new requirement—Organization requests approval for AB; submits documentation for assessing, approving, maintaining, and withdrawing accreditation of ASP (+48 hours).

—§ 250.1925(a)—The BSEE directed audit non-hour cost burdens were adjusted to be aligned with the audit costs in § 250.1920(a). We have determined that since an ASP will be part of the audit process, audits will be more objective; therefore, there will be less likelihood for as many BSEE-directed audits as was previously determined (−$15,000 non-hour cost burdens).

—§ 250.1926—Removed independent third-party requirements [-129 hours], but moved conflict of interest [+3 hours] to § 250.1922, for a total net reduction (−126 hours).

—§ 250.1932(d), (e)—Removed the requirement, upon request, to provide BSEE a copy of your EPP; make plan available during an audit (−43 hours).

—§ 250.1933(c)—[in this rule now § 250.1933(a)] Removed the requirement for employees to report unsafe practices and/or health violation since we have reporting of violations in current § 250.193 (−1 burden hour).

—§ 250.1933(f) [in this rule now § 250.1933(b)]—The requirement remains the same; recalculated the hour burden—Post notice where personnel can view their rights for reporting unsafe practices (−863 hours).

—§ 250.1933(h)—Removed—Create and distribute to all personnel unsafe activities card with relevant information (−10,500 hours).

The following requirement, § 250.1920(a), was in the proposed rule but the non-hour cost burdens for the requirements were inadvertently omitted from the burden table.

—§§ 250.1920(a), (b), and 250.1921—You must have your SEMS program audited by an ASP according to the requirements of this subpart and API RP 75, Section 12 (incorporated by reference as specified in § 250.198) within two years of the initial implementation of the SEMS program and at least once every three years thereafter. [Since we revised the requirement to no longer allow for in-house qualified personnel to lead an audit, we added non-hour cost burdens for each operator activity to cover the costs of engaging ASPs to conduct audits once every 3 years (+$974,000 non-hour cost burdens)].

This final rulemaking also removes all the non-hour cost burdens for the initial implementation of SEMS required by the existing Subpart S regulation. Operators were required to have their SEMS implemented by November 15, 2011, which was after this proposed rule was published, so BSEE had to account for the non-hour cost burdens in this proposed rule. Now that operators have implemented their SEMS, we no longer need to account for that non-hour cost burden; therefore, we removed the non-hour cost burdens pertaining to implementation (−$12,642,000).

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BURDEN TABLE

[*Italics show expansion/revision of existing requirements;* **bold indicates new requirements;** current regulations are regular font.]

Citation 30 CFR 250 Subpart A	Reporting and recordkeeping requirement	Hour burden	Average number of annual responses	Additional annual burden hours
193	Report possible hazardous, unsafe working conditions, violations, or non-compliance issues; if possible submit information/supporting documentation.	Burden included under 30 CFR 250, Subpart A—1010–0114.		0
Citation 30 CFR 250 Subpart S	**Reporting and recordkeeping requirement**	**Hour burden**	**Average number of annual responses**	**Additional annual burden hours**
1900–1933 *Expanded.*	High Activity Operator: Have a SEMS program, and maintain all documentation and records pertaining to your SEMS program, according to API RP 75, *ISO/IEC 17011* in *their* entirety, *the COS–2–01, 03, and 04 documents as listed in § 250.198, and all the requirements as detailed in 30 CFR 250, Subpart S.* Make your SEMS available to BSEE upon request.	18,708 *3,656*	13 operators	243,204 *47,528*
1900–1933 *Expanded.*	Moderate Activity Operator: Have a SEMS program, and maintain all documentation and records pertaining to your SEMS program, according to API RP 75, *the three COS documents* in *their* entirety, *and all the requirements as detailed in 30 CFR 250, Subpart S.* Make your SEMS available to BSEE upon request.	2,528 *2,393*	41 operators	103,648 *98,113*
1900–1933 *Expanded.*	Low Activity Operator: Have a SEMS program, and maintain all documentation and records pertaining to your SEMS program, according to API RP 75, *the three COS documents* in *their* entirety, *and all the requirements as detailed in 30 CFR 250, Subpart S.* Make your SEMS available to BSEE upon request.	899 *128*	76 operators	68,324 *9,728*
1928(d), (e); 1929.	Submit Form BSEE–0131. Maintain a contractor employee injury/illness log in the operation area, retain for 2 years, and make available to BSEE upon request (this requirement is included in the form burden). Inform contractors of hazards.	10	130 operators	1,300
1911(b) *Expanded.*	*Immediate* supervisor must conduct a JSA, *sign the JSA, and ensure all personnel participating sign the JSA. The individual designated as being in charge of facility approves and signs all JSAs before job starts.* *NOTE: If activity is repeated, the 1st signed JSA is allowed*	10 mins. *1 min.*	130 operators × 365 days × 6 = 284,700*	47,450 *4,745*
1920(a), (b); 1921 Revised.	*ASP audit for High Activity Operator* *ASP audit for Moderate Activity Operator* *ASP audit for Low Activity Operator* *NOTE: An audit once every 3 years.*	*13 operators × $60,000 audit = $780,000/3 = $260,000*		
		4l operators × $30,000 audit = $1,230,000/3 = $410,000		
		76 operators × $12,000 audit = $912,000/3 = $304,000		
1920	Notify BSEE with audit schedule 30 days prior to conducting your audit.	1	130 operators/ once every 3 years = 43	43 (rounded)
1920(c); 1925;	Submit to BSEE after completed audit, *an audit* report of findings and conclusions, including deficiencies and required supporting information/documentation.	3	44 operators	132
1920(d); *1925(b);*	Submit/*resubmit* a copy of your *CAP* that will address deficiencies identified in audit.	4	10 submissions	40

Citation 30 CFR 250 Subpart S	Reporting and recordkeeping requirement	Hour burden	Average number of annual responses	Additional annual burden hours
1922 NEW	**Organization requests approval for AB; submits documentation for assessing, approving, maintaining, and withdrawing accreditation of ASP.**	**16**	**3**	**48**
1922 NEW	**Make available to BSEE upon request, conflict of interest procedures.**	**15 mins**	**12 requests**	**3**
1924(b)	Make available to BSEE upon request, evaluation documentation and supporting information relating to your SEMS.	2	130 operators	260
1924(c)	Explain and demonstrate your SEMS during site visit if required; provide evidence supporting your SEMS implementation.	8	6 explanations	48
1925(a);	Pay for all costs associated with BSEE directed *ASP* audit approximately 10 percent per operator per category: 1 required audit for high operator ($60,000 per audit × 1 audit = $60,000); 4 required audits for moderate operator ($30,000 per audit × 4 audits = $120,000; and 8 required audits for low operator ($12,000 per audit per 8 audits = $96,000) = 13 required audits per year.	13 BSEE directed *ASP* audits—for a total of $276,000.		
1928 *Expanded*	(1) Document and keep all SEMS audits for 6 years (at least 2 full audit cycles) at an onshore location. (2) JSAs must have documented results in writing and kept onsite for 30 days, *or until release of the MODU*; retain records for 2 years. (3) All MOC records (API RP Sec 4) must be documented, dated, and retained for 2 years. *(4) SWA documentation must be kept onsite for 30 days; retain records for 2 years. (5) Documentation of employee participation must be retained for 2 years.* (6) All documentation included in this requirement must be made available to BSEE upon request.	5	130 operators	650
		2hrs/mo × 12 mos/yr = 24 hrs	*1,007 manned facilities*	*24,168*
		30 mins	*2,447 unmanned facilities*	*1,224 (rounded)*
1930(c) NEW	**Document decision to resume SWA activities**	**8**	**Once every 2 wks = 26**	**208**
1933(a) NEW	**Procedures for personnel reports unsafe practices and/or possible violations.**	**Burden covered under 30 CFR 250, Subpart A 1010–0114.**		**0**
1933(b) NEW	**Post notice where personnel can view reporting information pertaining to possible violations.**	**15 mins**	**3,454 facilities**	**864**
CURRENT SUBPART S BURDEN			285,469 Responses	465,099 Hours
			$12,933,000 Non-Hour Cost Burdens	
NEW and EXPANDED BURDEN added to 30 CFR 250, Subpart S			**6,946 responses**	**186,629 hours**
			$1,250,000 non-hour cost burdens	
COMBINED [current, new, and expanded] TOTAL SUBPART S			**292,415 Responses**	**651,728 Hours**
			$1,250,000 Non-Hour Cost Burdens	

* We calculated operators conducting six JSAs a day (3 JSAs for each 12-hour shift). Some contractors may perform none for a particular day, whereas others may conduct more than six per day. This estimate is an average.

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An agency may not conduct or sponsor, and you are not required to respond to, a collection of information unless it displays a currently valid OMB control number. The public may comment, at any time, on the accuracy of the IC burden in this rule and may submit any comments to DOI/BSEE; ATTN: Regulations and Standards

Branch; HE–3313; 381 Elden Street; Herndon, Virginia 20170–4817.

National Environmental Policy Act of 1969

This rule does not constitute a major Federal action significantly affecting the quality of the human environment. The BSEE has analyzed this final rule under the criteria of the National Environmental Policy Act and 516 Departmental Manual 15. This final rule meets the criteria set forth in 43 CFR 46.210 for a Departmental *Categorical Exclusion* in that this rule is ''* * * of an administrative, financial, legal, technical, or procedural nature * * *.'' This rule also meets the criteria set forth in 516 Departmental Manual 15.4(C)(1) for a BSEE *Categorical Exclusion* in that its impacts are limited to administrative, economic, or technological effects. Further, BSEE has analyzed this rule to determine if it meets any of the extraordinary circumstances that will require an environmental assessment or an environmental impact statement as set forth in 43 CFR 46.215.

Most sections of the rule address strictly administrative, technical, and/or procedural matters. Specific examples include definitions of terminology, scope and timing of documentation, recordkeeping, transfer of information, and general descriptions of what is to be included in written procedures. The rule does not create the potential for environmental effects as a result of new technologies, technology configurations, or technological procedures as such measures are not part of the rule. For aspects of the rule dealing with mechanical integrity and inspections, the requirements are procedural as the rule covers the content of the written procedures. While the rule identifies the requirement, it allows the operator to choose the means to accomplish the end as long as it is consistent with the SEMS requirements.

Other subsections require activities in addition to administrative tasks, advance planning, and procedural documentation, such as training, emergency response drills, and corrective procedural actions that address human errors identified in investigations. These requirements are also considered procedural in nature since the subsections describe general and ordered steps that operators must undertake to have and maintain a compliant SEMS program. Sections that require training or drilling of personnel are procedural in that they target the cognitive skills and knowledge of personnel (*e.g.,* § 250.1915(b)) and/or clarify the purpose and/or scope of training (*e.g.,* § 250.1918(c)). For example, in § 250.1918, BSEE requires training and drills for personnel to exercise elements in the Emergency Action Plan that focus on response, control, and evacuation procedures and reporting. The principal purpose of this is to ensure retention and refinement of the skills, knowledge, and abilities of personnel.

Each section and subsection has also been reviewed to ensure that no potentially relevant extraordinary circumstances apply to the final action that will warrant the preparation of an environmental assessment or environmental impact statement. All extraordinary circumstances were considered in accordance with 43 CFR 46.215, but only the following ones are potentially applicable:

(1) Have significant impacts on public health or safety.

(2) Establish a precedent for future action or represent a decision in principle about future actions with potentially significant environmental effects.

(3) Have a direct relationship to other actions with individually insignificant but cumulatively significant environmental effects.

The BSEE has analyzed this rule to determine if it meets any of the extraordinary circumstances that will require an Environmental Assessment or an Environmental Impact Statement as set forth in 516 Departmental Manual 2.3, and Appendix 2. The BSEE concluded that this rule does not meet any of the criteria for extraordinary circumstances as set forth in 43 CFR 46.215.

Data Quality Act

In developing this rule, we did not conduct or use a study, experiment, or survey requiring peer review under the Data Quality Act (Pub. L. 106–554, app. C § 515, 114 Stat. 2763, 2763A–153–154).

Effects on the Nation's Energy Supply (E.O. 13211)

This rule is not a significant energy action under the definition in E.O. 13211. A Statement of Energy Effects is not required.

List of Subjects in 30 CFR Part 250

Administrative practice and procedure, Continental shelf, Environmental protection, Incorporation by reference, Public Lands—mineral resources, Reporting and recordkeeping requirements.

Dated: March 28, 2013.

Tommy P. Beaudreau,

Acting Assistant Secretary—Land and Minerals Management.

For the reasons stated in the preamble, the Bureau of Safety and Environmental Enforcement (BSEE) is amending 30 CFR part 250 as follows:

PART 250—OIL AND GAS AND SULPHUR OPERATIONS IN THE OUTER CONTINENTAL SHELF

■ 1. The authority citation for 30 CFR part 250 continues to read as follows:

Authority: 30 U.S.C. 1751; 31 U.S.C. 9701; 43 U.S.C. 1334.

■ 2. In § 250.105, under the definition for ''facility,'' add paragraph (5) to read as follows:

§ 250.105 Definitions.

* * * * *

Facility means:

* * * * *

(5) As used in Subpart S of this part, all types of structures permanently or temporarily attached to the seabed (*e.g.,* mobile offshore drilling units (MODUs); floating production systems; floating production, storage and offloading facilities; tension-leg platforms; and spars) that are used for exploration, development, and production activities for oil, gas, or sulphur in the OCS. Facilities also include DOI-regulated pipelines.

* * * * *

■ 3. Revise § 250.193 to read as follows:

§ 250.193 Reports and investigations of possible violations.

(a) Any person may report to BSEE any hazardous or unsafe working condition on any facility engaged in OCS activities, and any possible violation or failure to comply with:

(1) Any provision of the Act,

(2) Any provision of a lease, approved plan, or permit issued under the Act,

(3) Any provision of any regulation or order issued under the Act, or

(4) Any other Federal law relating to safety of offshore oil and gas operations.

(b) To make a report under this section, a person is not required to know whether any legal requirement listed in paragraph (a) of this section has been violated.

(c) When BSEE receives a report of a possible violation, or when a BSEE employee detects a possible violation, BSEE will investigate according to BSEE procedures and notify any other Federal agency(ies) for further investigation, as appropriate.

(d) BSEE investigations of possible violations may include:

(1) Conducting interviews of personnel;

(2) Requiring the prompt production of documents, data, and other evidence;

(3) Requiring the preservation of all relevant evidence and access for BSEE investigators to such evidence; and

(4) Taking other actions and imposing other requirements as necessary to investigate possible violations and assure an orderly investigation.

(e)(1) Reports should contain sufficient credible information to establish a reasonable basis for BSEE to investigate whether a violation or other hazardous or unsafe working condition exists.

(2) To report hazardous or unsafe working conditions or a possible violation:

(i) Contact BSEE by:

(A) Phone at 1–877–440–0173 (BSEE Toll-free Safety Hotline),

(B) Internet at *www.bsee.gov,* or

(C) Mail to: U.S. DOI/BSEE, 1849 C Street NW., Mail Stop 5438, Herndon, VA 20240 Attention: IRU Hotline Operations.

(ii) Include the following items in the report:

(A) Name, address, and telephone number should be provided if you do not want to remain anonymous;

(B) The specific concern, provision or Federal law, if known, referenced in (a) that a person violated or with which a person failed to comply; and

(C) Any other facts, data, and applicable information.

(f) When a possible violation is reported, BSEE will protect a person's identity to the extent authorized by law.

■ 4. Amend § 250.198 by adding paragraphs (m) and (n) to read as follows:

§ 250.198 Documents incorporated by reference.

* * * * *

(m) International Organization for Standardization (ISO), 1, ch. De la Voi-Creuse, Case postale 56, CH–1211, Geneva 20, Switzerland; *www.iso.org;* phone: 41–22–749–01–11.

(1) ISO/IEC (International Electrotechnical Commission) 17011, Conformity assessment—General requirements for accreditation bodies accrediting conformity assessment bodies, First edition 2004–09–01; Corrected version 2005–02–15; incorporated by reference at §§ 250.1900, 250.1903, 250.1904, and 250.1922.

(2) [Reserved].

(n) Center for Offshore Safety (COS), 1990 Post Oak Blvd., Suite 1370, Houston, TX 77056; *www.centerforoffshoresafety.org;* phone: 832–495–4925.

(1) COS Safety Publication COS–2–01, Qualification and Competence Requirements for Audit Teams and Auditors Performing Third-party SEMS Audits of Deepwater Operations, First Edition, Effective Date October 2012; incorporated by reference at §§ 250.1900, 250.1903, 250.1904, and 250.1921.

(2) COS Safety Publication COS–2–03, Requirements for Third-party SEMS Auditing and Certification of Deepwater Operations, First Edition, Effective Date October 2012; incorporated by reference at §§ 250.1900, 250.1903, 250.1904, and 250.1920.

(3) COS Safety Publication COS–2–04, Requirements for Accreditation of Audit Service Providers Performing SEMS Audits and Certification of Deepwater Operations, First Edition, Effective Date October 2012; incorporated by reference at §§ 250.1900, 250.1903, 250.1904, and 250.1922.

■ 5. Amend § 250.1900 by:

■ a. Removing paragraphs (a) and (b),

■ b. Redesignating paragraphs (c) and (d) as (a) and (b) respectively, and

■ c. Revising newly redesignated paragraph (a) to read as follows:

§ 250.1900 Must I have a SEMS program?

* * * * *

(a) If there are any conflicts between the requirements of this subpart and API RP 75; COS–2–01, COS–2–03, or COS–2–04; or ISO/IEC 17011 (incorporated by reference as specified in § 250.198), you must follow the requirements of this subpart.

* * * * *

■ 6. In § 250.1901, revise paragraph (a) to read as follows:

§ 250.1901 What is the goal of my SEMS program?

* * * * *

(a) To accomplish this goal, you must ensure that your SEMS program identifies, addresses, and manages safety, environmental hazards, and impacts during the design, construction, start-up, operation (including, but not limited to, drilling and decommissioning), inspection, and maintenance of all new and existing facilities, including mobile offshore drilling units (MODUs) when attached to the seabed and Department of the Interior (DOI) regulated pipelines.

* * * * *

■ 7. Amend § 250.1902 by:

■ a. Revising paragraphs (a)(12) and (13),

■ b. Adding paragraphs (a)(14) through (17); and

■ c. Revising paragraph (b).

The revisions and additions read as follows:

§ 250.1902 What must I include in my SEMS program?

* * * * *

(a) * * *

(12) Auditing (Audit of Safety and Environmental Management Program Elements) (*see* § 250.1920)

(13) Recordkeeping (Records and Documentation) and additional BSEE requirements (*see* § 250.1928)

(14) Stop Work Authority (SWA) (see § 250.1930)

(15) Ultimate Work Authority (UWA) (see § 250.1931)

(16) Employee Participation Plan (EPP) (see § 250.1932)

(17) Reporting Unsafe Working Conditions (see § 250.1933).

(b) You must include a job safety analysis (JSA) for OCS activities identified or discussed in your SEMS program (see § 250.1911).

* * * * *

■ 8. Revise § 250.1903 to read as follows:

§ 250.1903 Acronyms and definitions.

Definitions listed in this section apply to this subpart and supersede definitions in API RP 75, Appendices D and E; COS–2–01, COS–2–03, and COS–2–04; and ISO/IEC 17011 (incorporated by reference as specified in § 250.198).

(a) *Acronyms* used frequently in this subpart have the following meanings:

AB means Accreditation Body,

ASP means Audit Service Provider,

CAP means Corrective Action Plan,

COS means Center for Offshore Safety,

EPP means Employee Participation Plan,

ISO means International Organization for Standardization,

JSA means Job Safety Analysis,

MODU means Mobile Offshore Drilling Unit,

OCS means Outer Continental Shelf,

SEMS means Safety and Environmental Management Systems,

SWA means Stop Work Authority,

USCG means United States Coast Guard, and

UWA means Ultimate Work Authority.

(b) *Terms* used in this subpart are listed alphabetically as follows:

Accreditation body (AB) means a BSEE-approved independent third-party organization that assesses and accredits ASPs.

Audit service provider (ASP) means an independent third-party organization that demonstrates competence to conduct SEMS audits in accordance with the requirements of this subpart.

Corrective action plan (CAP) means a scheduled plan to correct deficiencies

identified during an audit and that is developed by an operator following the issuance of an audit report.

Personnel means direct employee(s) of the operator and contracted workers.

Ultimate Work Authority (UWA) means the authority assigned to an individual or position to make final decisions relating to activities and operations on the facility.

■ 9. Revise § 250.1904 to read as follows:

§ 250.1904 Special instructions.

(a) For purposes of this subpart, each and every reference in COS–2–01, COS–2–03, and COS–2–04 (incorporated by reference as specified in § 250.198) to the term *deepwater* means the entire OCS, including all water depths.

(b) The BSEE does not incorporate by reference any requirement that you must be a COS member company. For purposes of this subpart, each and every reference in COS–2–01, COS–2–03, and COS–2–04 to the phrase *COS member company(ies)* means you, whether or not you are a COS member.

(c) For purposes of this subpart, each and every reference in the relevant sections of COS–2–01, COS–2–03, and COS–2–04 (incorporated by reference as specified in § 250.198) to the *Center for Offshore Safety* or *COS* means *accreditation body* or *AB.*

(d) For purposes of this subpart, each and every reference in ISO/IEC 17011 (incorporated by reference as specified in § 250.198) to *conformity assessment body (CAB)* means *ASP.*

■ 10. Amend § 250.1911 by:

■ a. Revising the section heading, the introductory text, and paragraphs (a) introductory text;

■ b. Adding paragraph (a)(4);

■ c. Revising paragraph (b); and

■ d. Adding paragraph (c).

The revisions and additions read as follows:

§ 250.1911 What hazards analysis criteria must my SEMS program meet?

You must ensure that a hazards analysis (facility level) and a JSA (operations/task level) are developed and implemented for all of your facilities and activities identified or discussed in your SEMS. You must document and maintain a current analysis for each operation covered by this section for the life of the operation at the facility. You must update the analysis when an internal audit is conducted to ensure that it is consistent with your facility's current operations.

(a) *Hazards Analysis (facility level).* The hazards analysis must be appropriate for the complexity of the operation and must identify, evaluate, and manage the hazards involved in the operation.

* * * * *

(4) A single hazards analysis can be performed to fulfill the requirements for simple and nearly identical facilities, such as well jackets and single well caissons. You can apply this single hazards analysis to simple and nearly identical facilities after you verify that any site-specific deviations are addressed in each of your SEMS program elements.

(b) *JSA.* You must ensure a JSA is prepared, conducted, and approved for OCS activities that are identified or discussed in your SEMS program. The JSA is a technique used to identify risks to personnel associated with their job activities. The JSAs are also used to determine the appropriate mitigation measures needed to reduce job risks to personnel. The JSA must include all personnel involved with the job activity.

(1) You must ensure that your JSA identifies, analyzes, and records:

(i) The steps involved in performing a specific job;

(ii) The existing or potential safety, health, and environmental hazards associated with each step; and

(iii) The recommended action(s) and/or procedure(s) that will eliminate or reduce these hazards, the risk of a workplace injury or illness, or environmental impacts.

(2) The immediate supervisor of the crew performing the job onsite must conduct the JSA, sign the JSA, and ensure that all personnel participating in the job understand and sign the JSA.

(3) The individual you designate as being in charge of the facility must approve and sign all JSAs before personnel start the job.

(4) If a particular job is conducted on a recurring basis, and if the parameters of these recurring jobs do not change, then the person in charge of the job may decide that a JSA for each individual job is not required. The parameters you must consider in making this determination include, but are not limited to, changes in personnel, procedures, equipment, and environmental conditions associated with the job.

(c) All personnel, which includes contractors, must be trained in accordance with the requirements of § 250.1915. You must also verify that contractors are trained in accordance with § 250.1915 prior to performing a job.

■ 11. In § 250.1914, revise the introductory text and paragraph (a) to read as follows:

§ 250.1914 What criteria must be documented in my SEMS program for safe work practices and contractor selection?

Your SEMS program must establish and implement safe work practices designed to minimize the risks associated with operations, maintenance, modification activities, and the handling of materials and substances that could affect safety or the environment. Your SEMS program must also document contractor selection criteria. When selecting a contractor, you must obtain and evaluate information regarding the contractor's safety record and environmental performance. You must ensure that contractors have their own written safe work practices. Contractors may adopt appropriate sections of your SEMS program. You and your contractor must document an agreement on appropriate contractor safety and environmental policies and practices before the contractor begins work at your facilities.

(a) A contractor is anyone performing work for you. However, these requirements do not apply to contractors providing domestic services to you or other contractors. Domestic services include janitorial work, food and beverage service, laundry service, housekeeping, and similar activities.

* * * * *

■ 12. In § 250.1915, revise the section heading, the introductory text, and paragraphs (c) and (d) to read as follows:

§ 250.1915 What training criteria must be in my SEMS program?

Your SEMS program must establish and implement a training program so that all personnel are trained in accordance with their duties and responsibilities to work safely and are aware of potential environmental impacts. Training must address such areas as operating procedures (§ 250.1913), safe work practices (§ 250.1914), emergency response and control measures (§ 250.1918), SWA (§ 250.1930), UWA (§ 250.1931), EPP (§ 250.1932), reporting unsafe working conditions (§ 250.1933), and how to recognize and identify hazards and how to construct and implement JSAs (§ 250.1911). You must document your instructors' qualifications. Your SEMS program must address:

* * * * *

(c) Communication requirements to ensure that personnel will be informed of and trained as outlined in this section whenever a change is made in any of the areas in your SEMS program that impacts their ability to properly understand and perform their duties and responsibilities. Training and/or

notice of the change must be given before personnel are expected to operate the facility.

(d) How you will verify that the contractors are trained in the work practices necessary to understand and perform their jobs in a safe and environmentally sound manner in accordance with all provisions of this section.

■ 13. Amend § 250.1920 by revising paragraphs (a), (b)(5), (b)(6), (c), and (d) and removing paragraph (e).

The revisions read as follows:

§ 250.1920 What are the auditing requirements for my SEMS program?

(a) Your SEMS program must be audited by an accredited ASP according to the requirements of this subpart and API RP 75, Section 12 (incorporated by reference as specified in § 250.198). The audit process must also meet or exceed the criteria in Sections 9.1 through 9.8 of *Requirements for Third-party SEMS Auditing and Certification of Deepwater Operations* COS–2–03 (incorporated by reference as specified in § 250.198) or its equivalent. Additionally, the audit team lead must be an employee, representative, or agent of the ASP, and must not have any affiliation with the operator. The remaining team members may be chosen from your personnel and those of the ASP. The audit must be comprehensive and include all elements of your SEMS program. It must also identify safety and environmental performance deficiencies.

(b) * * *

(5) Section 12.5 Audit Frequency, except your audit interval, must not exceed 3 years after the 2-year time period for the first audit. The 3-year auditing cycle begins on the start date of each comprehensive audit (including the initial implementation audit) and ends on the start date of your next comprehensive audit.

(6) Section 12.6 Audit Team. Your audits must be performed by an ASP as described in § 250.1921. You must include the ASP's qualifications in your audit plan.

(c) You must submit an audit report of the audit findings, observations, deficiencies identified, and conclusions to BSEE within 60 days of the audit completion date.

(d) You must provide BSEE with a copy of your CAP for addressing the deficiencies identified in your audit within 60 days of the audit completion date. Your CAP must include the name and job title of the personnel responsible for correcting the identified deficiency(ies). The BSEE will notify you as soon as practicable after receipt of your CAP if your proposed schedule is not acceptable or if the CAP does not effectively address the audit findings.

■ 14. Add §§ 250.1921 and 250.1922 to read as follows:

§ 250.1921 What qualifications must the ASP meet?

(a) The ASP must meet or exceed the qualifications, competency, and training criteria contained in Section 3 and Sections 6 through 10 of *Qualification and Competence Requirements for Audit Teams and Auditors Performing Third-party SEMS Audits of Deepwater Operations,* COS–2–01, (incorporated by reference as specified in § 250.198) or its equivalent;

(b) The ASP must be accredited by a BSEE-approved AB; and

(c) The ASP must perform an audit in accordance with 250.1920(a).

§ 250.1922 What qualifications must an AB meet?

(a) In order for BSEE to approve an AB, the organization must satisfy the requirements of the International Organization for Standardization's (ISO/IEC 17011) *Conformity assessment—General requirements for accreditation bodies accrediting conformity assessment bodies,* First Edition 2004–09–01; Corrected Version 2005–02–15 (incorporated by reference as specified in § 250.198) or its equivalent.

(1) The AB must have an accreditation process that meets or exceeds the requirements contained in Section 6 of *Requirements for Accreditation of Audit Service Providers Performing SEMS Audits and Certification of Deepwater Operations,* COS–2–04 (incorporated by reference as specified in § 250.198) or its equivalent, and other requirements specified in this subpart. Organizations requesting approval must submit documentation to BSEE describing the process for assessing an ASP for accreditation and approving, maintaining, and withdrawing the accreditation of an ASP. Requests for approval must be sent to DOI/BSEE, ATTN: Chief, Office of Offshore Regulatory Programs, 381 Elden Street, HE–3314, Herndon, VA 20170.

(2) An AB may be subject to BSEE audits and other requirements deemed necessary to verify compliance with the accreditation requirements.

(b) An AB must have procedures in place to avoid conflicts of interest with the ASP and make such information available to BSEE upon request.

■ 15. Amend § 250.1924 by revising paragraphs (a) and (b)(2) and removing paragraph (d).

The revisions read as follows:

§ 250.1924 How will BSEE determine if my SEMS program is effective?

(a) The BSEE, or its authorized representative, may evaluate or visit your facility(ies) to determine whether your SEMS program is in place, addresses all required elements, is effective in protecting worker safety and health and the environment, and preventing incidents. The BSEE, or its authorized representative, may evaluate any and all aspects of your SEMS program as outlined in this subpart. These evaluations or visits may be random and may be based upon your performance or that of your contractors.

(b) * * *

(2) Your audit team's qualifications.

* * * * *

■ 16. Revise § 250.1925 to read as follows:

§ 250.1925 May BSEE direct me to conduct additional audits?

(a) The BSEE may direct you to have an ASP audit of your SEMS program if BSEE identifies safety or non-compliance concerns based on the results of our inspections and evaluations, or as a result of an event. This BSEE-directed audit is in addition to the regular audit required by § 250.1920. Alternatively, BSEE may conduct an audit.

(1) If BSEE directs you to have an ASP audit, you are responsible for all of the costs associated with the audit, and

(i) The ASP must meet the requirements of §§ 250.1920 and 250.1921 of this subpart.

(ii) You must submit an audit report of the audit findings, observations, deficiencies identified, and conclusions to BSEE within 60 days of the audit completion date.

(2) If BSEE conducts the audit, BSEE will provide you with a report of the audit findings, observations, deficiencies identified, and conclusions as soon as practicable.

(b) You must provide BSEE a copy of your CAP for addressing the deficiencies identified in the BSEE-directed audit within 60 days of the audit completion date. Your CAP must include the name and job title of the personnel responsible for correcting the identified deficiency(ies). The BSEE will notify you as soon as practicable after receipt of your CAP if your proposed schedule is not acceptable or if the CAP does not effectively address the audit findings.

§ 250.1926 [Removed and Reserved]

■ 17. Remove and reserve § 250.1926

■ 18. Amend § 250.1928 by:

■ a. Revising paragraph (b);

■ b. Redesignating paragraph (f) as paragraph (h); and

■ c. Adding new paragraphs (f) and (g).

The revision and additions read as follows:

§ 250.1928 What are my recordkeeping and documentation requirements?

* * * * *

(b) For JSAs, the person in charge of the job must document the results of the JSA in writing and must ensure that records are kept onsite for 30 days. In the case of a MODU, records must be kept onsite for 30 days or until you release the MODU, whichever comes first. You must retain these records for 2 years and make them available to BSEE upon request.

* * * * *

(f) For SWA, you must document all training and reviews required by § 250.1930(e). You must ensure that these records are kept onsite for 30 days. In the case of a MODU, records must be kept onsite for 30 days or until you release the MODU, whichever comes first. You must retain these records for 2 years and make them available to BSEE upon request.

(g) For EPP, you must document your employees' participation in the development and implementation of the SEMS program. You must retain these records for 2 years and make them available to BSEE upon request.

* * * * *

■ 20. Add §§ 250.1930 through 250.1933 to read as follows:

§ 250.1930 What must be included in my SEMS program for SWA?

(a) Your SWA procedures must ensure the capability to immediately stop work that is creating imminent risk or danger. These procedures must grant all personnel the responsibility and authority, without fear of reprisal, to stop work or decline to perform an assigned task when an imminent risk or danger exists. Imminent risk or danger means any condition, activity, or practice in the workplace that could reasonably be expected to cause:

(1) Death or serious physical harm; or

(2) Significant environmental harm to:

(i) Land;

(ii) Air; or

(iii) Mineral deposits, marine, coastal, or human environment.

(b) The person in charge of the conducted work is responsible for ensuring the work is stopped in an orderly and safe manner. Individuals who receive a notification to stop work must comply with that direction immediately.

(c) Work may be resumed when the individual on the facility with UWA determines that the imminent risk or danger does not exist or no longer exists. The decision to resume activities must be documented in writing as soon as practicable.

(d) You must include SWA procedures and expectations as a standard statement in all JSAs.

(e) You must conduct training on your SWA procedures as part of orientations for all new personnel who perform activities on the OCS. Additionally, the SWA procedures must be reviewed during all meetings focusing on safety on facilities subject to this subpart.

§ 250.1931 What must be included in my SEMS program for UWA?

(a) Your SEMS program must have a process to identify the individual with the UWA on your facility(ies). You must designate this individual taking into account all applicable USCG regulations that deal with designating a person in charge of an OCS facility. Your SEMS program must clearly define who is in charge at all times. In the event that multiple facilities, including a MODU, are attached and working together or in close proximity to one another to perform an OCS operation, your SEMS program must identify the individual with the UWA over the entire operation, including all facilities.

(b) You must ensure that all personnel clearly know who has UWA and who is in charge of a specific operation or activity at all times, including when that responsibility shifts to a different individual.

(c) The SEMS program must provide that if an emergency occurs that creates an imminent risk or danger to the health or safety of an individual, the public, or to the environment (as specified in § 250.1930(a)), the individual with the UWA is authorized to pursue the most effective action necessary in that individual's judgment for mitigating and abating the conditions or practices causing the emergency.

§ 250.1932 What are my EPP requirements?

(a) Your management must consult with their employees on the development, implementation, and modification of your SEMS program.

(b) Your management must develop a written plan of action regarding how your appropriate employees, in both your offices and those working on offshore facilities, will participate in your SEMS program development and implementation.

(c) Your management must ensure that employees have access to sections of your SEMS program that are relevant to their jobs.

§ 250.1933 What procedures must be included for reporting unsafe working conditions?

(a) Your SEMS program must include procedures for all personnel to report unsafe working conditions in accordance with § 250.193. These procedures must take into account applicable USCG reporting requirements for unsafe working conditions.

(b) You must post a notice at the place of employment in a visible location frequently visited by personnel that contains the reporting information in § 250.193.

[FR Doc. 2013–07738 Filed 4–4–13; 8:45 am]

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DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 103

[DoD–2008–OS–0124; 0790–AI37]

Sexual Assault Prevention and Response (SAPR) Program

AGENCY: Department of Defense.

ACTION: Final rule.

SUMMARY: This part implements Department of Defense (DoD) policy and assigns responsibilities for the SAPR Program on prevention, response, and oversight to sexual assault. It is DoD policy to establish a culture free of sexual assault by providing an environment of prevention, education and training, response capability, victim support, reporting procedures, and accountability that enhances the safety and wellbeing of all persons covered by this regulation.

DATES: This rule is effective April 5, 2013.

FOR FURTHER INFORMATION CONTACT: Diana Rangoussis, Senior Policy Advisor, Sexual Assault Prevention and Response Office (SAPRO), (703) 696–9422.

SUPPLEMENTARY INFORMATION:

Executive Summary

This rule:

a. Incorporates all applicable congressional mandates from Section 113 of Title 10, United States Code (U.S.C.), and Public Laws 109–364, 109–163, 108–375, 106–65, 110–417, and 111–84; and all applicable recommendations from the IG, DoD; Government Accountability Office; and Defense Task Force on Sexual Assault in the Military Services;

b. Establishes the creation, implementation, maintenance, and

function of DSAID, an integrated database that will meet congressional reporting requirements, support Military Service SAPR Program management, and inform DoD SAPRO oversight activities;

c. Increases the scope of applicability of this part by expanding the categories of persons covered by this part to include:

1. National Guard and Reserve Component members who are sexually assaulted when performing active service, as defined in section 101(d)(3) of Title 10, U.S.C., and inactive duty training. Refer to DoD Instruction (DoDI) 6495.02 for additional SAPR and medical services provided to such personnel and eligibility criteria for Restricted Reporting;

2. Military dependents 18 years of age and older who are eligible for treatment in the military healthcare system, at installations in the continental United States (CONUS) and outside of the continental United States (OCONUS), and who were victims of sexual assault perpetrated by someone other than a spouse or intimate partner. (The Family Advocacy Program (FAP), pursuant to DoD Directive (DoDD) 6400.1, covers military dependent sexual assault victims who are assaulted by a spouse or intimate partner and military dependent sexual assault victims who are 17 years of age and younger). The installation SARC and the installation family advocacy program (FAP) and domestic violence intervention and prevention staff shall direct coordination when a sexual assault occurs within a domestic relationship or involves child abuse;

3. The following non-military personnel who are only eligible for limited medical services in the form of emergency care (see § 103.3(g) of this rule), unless otherwise eligible to receive treatment in a military medical treatment facility. They will also be offered the limited SAPR services of a Sexual Assault Response Coordinator (SARC) and a SAPR Victim Advocate (VA) while undergoing emergency care OCONUS. Refer to DoDI 6495.02 for any additional SAPR and medical services provided. These limited medical and SAPR services shall be provided to:

i. DoD civilian employees and their family dependents 18 years of age and older when they are stationed or performing duties OCONUS and eligible for treatment in the military healthcare system at military installations or facilities OCONUS. Refer to DoDI 6495.02 for reporting options available to DoD civilians and their family dependents 18 years of age and older;

ii. U.S. citizen DoD contractor personnel when they are authorized to accompany the Armed Forces in a contingency operation OCONUS and their U.S. citizen employees per DoDI 3020.41. Refer to DoDI 6495.02 for reporting options available to DoD contractors; and

4. Service members who are on active duty but were victims of sexual assault prior to enlistment or commissioning. They are eligible to receive full SAPR services and either reporting option. The focus of this part and DoDI 6495.02 is on the victim of sexual assault. The DoD shall provide support to an active duty Service member regardless of when or where the sexual assault took place.

The preliminary estimate of the anticipated cost associated with this rule is approximately $14,819 million. The $14,819 million only refers to the SAPR budget allocated to DoD SAPRO. Each individual Service POMs for their own SAPR funding. Each of the Military Services establishes its own SAPR budget for the programmatic costs arising from the implementation of the training, prevention, reporting, response, oversight and staffing requirements established by this rule.

Public Comments

The Department of Defense published an interim final rule on January 27, 2012 (77 FR 4239) with a request for public comments. Five sets of public comments were received and are addressed below:

Comment: A public submission was received February 23, 2012, tracking number 80fbdd69, that only provided a green highlighted section of the rule in the definition for the Defense Sexual Assault Incident Database (DSAID).

Response: The highlighted portion was provided in the rule; however, there were not questions or comments posted with this submission.

Comment: A second public submission was received March 7, 2012, tracking number 80fd0bf8, remarking that while it may be difficult to determine a specific timeline, it is critical that the required response time must not be at all vague. It must be clear that a SARC will be notified and transportation to the exam site, with patient consent, will happen immediately when a report of a sexual assault is made and the timing must be specific. This will further establish the DoD's commitment to victim support and advocacy. A second comment provided stated, ''If the DoD is truly committed to prevention of sexual assault, victim support and advocacy, and ensuring the safety of all person covered by the regulation, then its Prevention Strategy should be described in detail and outlined first instead of last in the regulation.''

Response: As stated in this rule, the Department recognizes the need for ''immediate medical intervention to prevent loss of life or undue suffering.'' While the rule is prescriptive in the type of care victims shall receive, the unique and unpredictable circumstances in some environments, such as deployed locations, preclude the Department from assigning a fixed timeline. For example, some locations require Sexual Assault Prevention and Response (SAPR) first responders to meet the needs of the victim while also avoiding other threats that present themselves, such as in combat areas, where immediate transportation may present an undue threat to the victim's physical safety. In response to the DoD Prevention Strategy being described in detailed and outlined with this rule, the culture of the U.S. Armed Forces changes over time, as in the broader U.S. population, and thus the specific methods and initiatives best suited for fostering a culture free of sexual assault and an environment of prevention may also change over time. Keeping information in the rule about the Department's prevention strategy high level allows the rule to remain flexible and gives the Department latitude to adjust its prevention methodologies over time to maintain effectiveness in an ever-changing military culture.

Comment: A third comment was posted March 29, 2012, tracking number 80fe2c5d, stating that the interim final rule should be amended to expand full SAPR coverage to all DoD employed civilians regardless of where they are stationed. Additionally all DoD contractors operating outside of the Continental United States (OCONUS) should have full access to SAPR programs. The interim final rule should also require SAPR training of all DoD employees, uniformed and civilian. Where the DoD chooses to hire OCONUS contractors to assist uniformed service personnel, the contractors should also receive basic sexual assault training by SAPR or a comparable program. Issues pertaining to the operation of SAPR OCONUS also need to be revisited before issuance of the final rule.

Response: The Department of Defense (DoD) provides sexual assault prevention and response (SAPR) services to DoD civilian employees and U.S. citizen DoD contractor personnel only when they are stationed or performing duties outside the continental United States (OCONUS) because they do not have access to their regular civilian response and support

resources (e.g. medical care, victim advocacy services) while abroad. When stationed within the continental United States, they have access to civilian response and support resources just as other civilians do. With regard to implementation of the SAPR Program OCONUS, the rule requires a 24/7 sexual assault response capability for all locations, including deployed areas.

Comment: A fourth comment was submitted March 29, 2012, tracking number 80fe2c64, stating that although restricted reporting prevents a commanding officer from being provided with a name of the victim, the commanding officer is still told of an assault for safety reasons. The commanding officer will likely find out the name of the victim. Therefore, this proposed rule does not change the reason why so many people chose not to report. Victims choose not to report out of fear that they will not be believed, concerns about privacy, shame and blame associated with the crime, and belief that police can't do anything about the crime.

Response: Increasing victim confidence in the reporting process continues to be a priority for the Department of Defense (DoD) and we will continue to work to identify barriers to reporting sexual assaults and address them. Since the implementation of the Restricted Reporting option in 2005, Service member victim reports of sexual assault have grown steadily; total reports of sexual assault made to the Department have also increased. The rule explicitly states that a victim's Restricted Report will not be reported to law enforcement or the victim's command unless the victim consents or an established exception applies. According to the Rule, ''[i]mproper disclosure of confidential communications under Restricted Reporting, improper release of medical information, and other violations of this policy are prohibited and may result in discipline pursuant to the UCMJ, or other adverse personnel or administrative actions.'' The Department continues working to understand and address barriers to reporting; e.g. the victim may fear retaliation from the chain of command or harsh judgments; or that s/he will be viewed as a trouble-maker; the victim may fear being the subject of blame, mockery or harassment; additional details will also be provided when DoD Instruction 6495.02 is reissued.

Regulatory Procedures

Executive Order 12866, ''Regulatory Planning and Review'' and Executive Order 13563, ''Improving Regulation and Regulatory Review''

It has been determined that this rule is not an economically significant regulatory action. The rule 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 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 these Executive Orders.
5. The definition of ''sexual assault'' has been revised to reflect the changes to the Uniform Code of Military Justice (UCMJ) mandated in the NDAA FY 12. The modifications to the definition are not significant changes to the definition and do not change program administration or coverage DoD needs. The definition was updated to reflect changes in the following punitive offenses—''Aggravated Sexual Assault'' is now ''Sexual Assault'' and ''Wrongful Sexual Contact'' is deleted and incorporated into Aggravated Sexual Contact and Abusive Sexual Contact.

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

It has been certified that this rule does not contain a Federal mandate that may result in the expenditure by State, local and tribal 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 this rule 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. This rule provides SAPR Program guidance only.

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

It has been certified that this rule does impose reporting or recordkeeping requirements under the Paperwork Reduction Act of 1995.OMB has approved these requirements under OMB Control Number 0704–0482. The System of Records Notice for the rule is located at *http://www.sapr.mil/media/pdf/dsaid/DSAID_Federal_Register_SORN.pdf*. The Privacy Act Information for this rule is located at *http://www.whs.mil/EITSD/documents/DSAID-PIA.pdf*.

Executive Order 13132, ''Federalism''

It has been certified that this rule does not have federalism implications, as set forth in Executive Order 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 103

Military personnel, crime, health.

Accordingly, 32 CFR part 103 is revised to read as follows:

PART 103—SEXUAL ASSAULT PREVENTION AND RESPONSE (SAPR) PROGRAM

Sec.
103.1 Purpose.
103.2 Applicability.
103.3 Definitions.
103.4 Policy.
103.5 Responsibilities.

Authority: 10 U.S.C. 113; and Public Laws 109–364, 109–163, 108–375, 106–65, 110–417, and 111–84.

§ 103.1 Purpose.

(a) This part reissues DoDD 6495.01, pursuant to section 113 of Title 10, U.S.C., to implement DoD policy and assign responsibilities for the SAPR Program on prevention, response, and oversight to sexual assault according to the guidance in:

(1) This part;

(2) DoDD 6495.01, ''Sexual Assault Prevention and Response (SAPR) Program,'' October 6, 2005 (hereby cancelled);

(3) Sections 101(d)(3) and 113, chapter 47,[1] and chapter 80 of title 10, U.S.C.;

(4) DoDI 6495.02, ''Sexual Assault Prevention and Response Program Procedures,'' November 13, 2008 found at *http://www.dtic.mil/whs/directives/corres/pdf/649502p.pdf;*

(5) DoDD 6400.1, ''Family Advocacy Program (FAP),'' August 23, 2004 found at *http://www.dtic.mil/whs/directives/corres/pdf/640001p.pdf;*

[1] Also known as ''The Uniform Code of Military Justice.''

(6) DoD Instruction 5025.01, ''DoD Directives Program,'' September 26, 2012 found at *http://www.dtic.mil/whs/directives/corres/pdf/502512p.pdf;*

(7) DoD Instruction 3020.41, ''Operational Contract Support (OCS),'' December 20, 2011 found at *http://www.dtic.mil/whs/directives/corres/pdf/302041p.pdf;*

(8) U.S. Department of Defense, ''Manual for Courts-Martial,'' 2008;

(9) DoDD 7050.06, ''Military Whistleblower Protection,'' July 23, 2007 found at *http://www.dtic.mil/whs/directives/corres/pdf/705006p.pdf;*

(10) U.S. Department of Justice, Office on Violence Against Women, ''A National Protocol for Sexual Assault Medical Forensic Examinations, Adults/Adolescents,'' September 2004, or the most recent edition;

(11) DoDD 5400.11, ''DoD Privacy Program,'' May 8, 2007 found at *http://www.dtic.mil/whs/directives/corres/pdf/540011p.pdf;*

(12) DoD 6025.18–R, ''DoD Health Information Privacy Regulation,'' January 24, 2003 found at *http://www.dtic.mil/whs/directives/corres/pdf/602518r.pdf;*

(13) DoD 8910.1–M, ''DoD Procedures for Management of Information Requirements,'' June 30, 1998 found at *http://www.dtic.mil/whs/directives/corres/pdf/891001m.pdf;*

(14) DoDD 5124.02, ''Under Secretary of Defense for Personnel and Readiness (USD(P&R)),'' June 23, 2008 found at *http://www.dtic.mil/whs/directives/corres/pdf/512402p.pdf;*

(15) U.S. Department of Defense paper, ''The Department of Defense Sexual Assault Prevention Strategy,'' September 30, 2008;

(16) Section 577 of Public Law 108–375, ''Ronald Reagan National Defense Authorization Act for Fiscal Year 2005,'' October 28, 2004;

(17) Sections 561, 562, and 563 of Public Law 110–417, ''The Duncan Hunter National Defense Authorization Act for Fiscal Year 2009,'' October 14, 2008;

(18) Section 567(c) of Public Law 111–84, ''The National Defense Authorization Act for Fiscal Year 2010,'' October 28, 2009;

(19) Joint Publication 1–02, ''Department of Defense Dictionary of Military and Associated Terms,'' current edition found at *http://www.dtic.mil/doctrine/new_pubs/jp1_02.pdf;* and

(20) DoD Instruction 5545.02, ''DoD Policy for Congressional Authorization and Appropriations Reporting Requirement,'' December 19, 2008 found at *http://www.dtic.mil/whs/directives/corres/pdf/554502p.pdf.*

(b) [Reserved]

§ 103.2 Applicability.

This part applies to:

(a) OSD, the Military Departments, the Office of the Chairman of the Joint Chiefs of Staff and the Joint Staff, the Combatant Commands, the IG, DoD, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the DoD (hereafter referred to collectively as the ''DoD Components'').

(b) National Guard, and Reserve Component members who are sexually assaulted when performing active service, as defined in section 101(d)(3) of Title 10, U.S.C., and inactive duty training. Refer to DoDI 6495.02 for additional SAPR and medical services provided to such personnel and eligibility criteria for Restricted Reporting.

(c) Military dependents 18 years of age and older, who are eligible for treatment in the military healthcare system, at installations in the continental United States (CONUS) and outside of the continental United States (OCONUS), and who were victims of sexual assault perpetrated by someone other than a spouse or intimate partner. (The FAP, pursuant to DoDD 6400.1, covers adult military dependent sexual assault victims who are assaulted by a spouse or intimate partner and military dependent sexual assault victims who are 17 years of age and younger.) The FAP Program provides the full range of services provided to victims of domestic violence to victims who are sexually assaulted, in violation of Articles 120 (Rape and Sexual Assault) and 125 (Sodomy), UCMJ, by someone with whom they have an intimate partner relationship. The installation SARC and the installation family advocacy program (FAP) and domestic violence intervention and prevention staff shall direct coordination when a sexual assault occurs within a domestic relationship or involves child abuse.

(d) The following non-military personnel, who are only eligible for limited medical services in the form of emergency care (see § 103.3 of this part), unless otherwise eligible to receive treatment in a military medical treatment facility. They will also be offered the limited SAPR services of a SARC and a SAPR VA while undergoing emergency care OCONUS. Refer to DoDI 6495.02 for any additional SAPR and medical services provided. These limited medical and SAPR services shall be provided to:

(1) DoD civilian employees and their family dependents 18 years of age and older when they are stationed or performing duties OCONUS and eligible for treatment in the military healthcare system at military installations or facilities OCONUS. Refer to DoDI 6495.02 for reporting options available to DoD civilians and their family dependents 18 years of age and older; and

(2) U.S. citizen DoD contractor personnel when they are authorized to accompany the Armed Forces in a contingency operation OCONUS and their U.S. citizen employees per DoDI 3020.41. Refer to DoDI 6495.02 for reporting options available to DoD contractors.

(e) Service members who are on active duty but were victims of sexual assault prior to enlistment or commissioning. They are eligible to receive SAPR services and either reporting option. The focus of this part and DoDI 6495.02 is on the victim of sexual assault. The DoD shall provide support to an active duty Service member regardless of when or where the sexual assault took place.

(f) Supersedes all policy and regulatory guidance within the DoD not expressly mandated by law that is inconsistent with its provisions, or that would preclude execution.

§ 103.3 Definitions.

Unless otherwise noted, these terms and their definitions are for the purpose of this part.

Confidential communication. Oral, written, or electronic communications of personally identifiable information concerning a sexual assault victim and the sexual assault incident provided by the victim to the SARC, SAPR VA, or healthcare personnel in a Restricted Report. This confidential communication includes the victim's sexual assault forensic examination (SAFE) Kit and its information. See *http://www.archives.gov/cui.*

Consent. Words or overt acts indicating a freely given agreement to the sexual conduct at issue by a competent person. An expression of lack of consent through words or conduct means there is no consent. Lack of verbal or physical resistance or submission resulting from the accused's use of force, threat of force, or placing another person in fear does not constitute consent. A current or previous dating relationship or the manner of dress of the person involved with the accused in the sexual conduct at issue shall not constitute consent. There is no consent where the person is sleeping or incapacitated, such as due to age, alcohol or drugs, or mental incapacity.

Crisis intervention. Emergency non-clinical care aimed at assisting victims in alleviating potential negative consequences by providing safety

assessments and connecting victims to needed resources. Either the SARC or SAPR VA will intervene as quickly as possible to assess the victim's safety and determine the needs of victims and connect them to appropriate referrals, as needed.

Culturally-competent care. Care that provides culturally and linguistically appropriate services.

DSAID. A DoD database that captures uniform data provided by the Military Services and maintains all sexual assault data collected by the Military Services. This database shall be a centralized, case-level database for the uniform collection of data regarding incidence of sexual assaults involving persons covered by this part and DoDI 6495.02. DSAID will include information when available, or when not limited by Restricted Reporting, or otherwise prohibited by law, about the nature of the assault, the victim, the offender, and the disposition of reports associated with the assault. DSAID shall be available to the Sexual Assault and Response Office and the DoD to develop and implement congressional reporting requirements. Unless authorized by law, or needed for internal DoD review or analysis, disclosure of data stored in DSAID will only be granted when disclosure is ordered by a military, Federal, or State judge or other officials or entities as required by a law or applicable U.S. international agreement. This term and its definition are proposed for inclusion in the next edition of Joint Publication 1–02.

Emergency. A situation that requires immediate intervention to prevent the loss of life, limb, sight, or body tissue to prevent undue suffering. Regardless of appearance, a sexual assault victim needs immediate medical intervention to prevent loss of life or undue suffering resulting from physical injuries internal or external, sexually transmitted infections, pregnancy, or psychological distress. Sexual assault victims shall be given priority as emergency cases regardless of evidence of physical injury.

Emergency care. Emergency medical care includes physical and emergency psychological medical services and a SAFE consistent with the U.S. Department of Justice, Office on Violence Against Women Protocol.

Gender-responsive care. Care the acknowledges and is sensitive to gender differences and gender-specific issues.

Healthcare personnel. Persons assisting or otherwise supporting healthcare providers in providing healthcare services (e.g., administrative personnel assigned to a military medical treatment facility, or mental healthcare personnel). Healthcare personnel also includes all healthcare providers.

Military Services. The term, as used in the SAPR Program, includes Army, Air Force, Navy, Marines, Reserve Components, and their respective Military Academies.

Non-identifiable personal information. Non-identifiable personal information includes those facts and circumstances surrounding the sexual assault incident or that information about the individual that enables the identity of the individual to remain anonymous. In contrast, personal identifiable information is information belonging to the victim and alleged assailant of a sexual assault that would disclose or have a tendency to disclose the person's identity.

Official investigative process. The formal process a commander or law enforcement organization uses to gather evidence and examine the circumstances surrounding a report of sexual assault.

Personal identifiable information. Includes the person's name, other particularly identifying descriptions (e.g., physical characteristics or identity by position, rank, or organization), or other information about the person or the facts and circumstances involved that could reasonably be understood to identify the person (e.g., a female in a particular squadron or barracks when there is only one female assigned).

Qualifying conviction. A State or Federal conviction, or a finding of guilty in a juvenile adjudication, for a felony crime of sexual assault and any general or special court-martial conviction for a Uniform Code of Military Justice (UCMJ) offense, which otherwise meets the elements of a crime of sexual assault, even though not classified as a felony or misdemeanor within the UCMJ. In addition, any offense that requires registration as a sex offender is a qualifying conviction.

Recovery-oriented care. Focus on the victim and on doing what is necessary and appropriate to support victim recovery, and also, if a Service member, to support that Service member to be fully mission capable and engaged.

Restricted reporting. Reporting option that allows sexual assault victims to confidentially disclose the assault to specified individuals (i.e., SARC, SAPR VA, or healthcare personnel), in accordance with ''Victim Centered Care'' of U.S. Department of Justice, Office on Violence Against Women, ''A National Protocol for Sexual Assault Medical Forensic Examinations, Adults/Adolescents'' and receive medical treatment, including emergency care, counseling, and assignment of a SARC and SAPR VA, without triggering an official investigation. The victim's report provided to healthcare personnel (including the information acquired from a SAFE Kit), SARCs, or SAPR VAs will not be reported to law enforcement or to the command to initiate the official investigative process unless the victim consents or an established exception applies in accordance with DoDI 6495.02. The Restricted Reporting Program applies to Service Members and their military dependents 18 years of age and older. For additional persons who may be entitled to Restricted Reporting, see eligibility criteria in DoDI 6495.02. Only a SARC, SAPR VA, or healthcare personnel may receive a Restricted Report, previously referred to as Confidential Reporting. This term and its definition are proposed for inclusion in the next edition of Joint Publication 1–02.

SAFE Kit. The medical and forensic examination of a sexual assault victim under circumstances and controlled procedures to ensure the physical examination process and the collection, handling, analysis, testing, and safekeeping of any bodily specimens and evidence meet the requirements necessary for use as evidence in criminal proceedings. The victim's SAFE Kit is treated as a confidential communication when conducted as part of a Restricted Report. This term and its definition are proposed for inclusion in the next edition of Joint Publication 1–02.

SAPRO. Serves as DoD's single point of authority, accountability, and oversight for the SAPR program, except for legal processes and criminal investigative matters that are the responsibility of the Judge Advocates General of the Military Departments and the IG respectively. This term and its definition are proposed for inclusion in the next edition of Joint Publication 1–02.

SAPR Program. A DoD program for the Military Departments and the DoD Components that establishes SAPR policies to be implemented worldwide. The program objective is an environment and military community intolerant of sexual assault. This term and its definition are proposed for inclusion in the next edition of Joint Publication 1–02.

SAPR VA. A person who, as a victim advocate, shall provide non-clinical crisis intervention, referral, and ongoing non-clinical support to adult sexual assault victims. Support will include providing information on available options and resources to victims. The SAPR VA, on behalf of the sexual assault victim, provides liaison

assistance with other organizations and agencies on victim care matters and reports directly to the SARC when performing victim advocacy duties. Personnel who are interested in serving as a SAPR VA are encouraged to volunteer for this duty assignment. This term and its definition are proposed for inclusion in the next edition of Joint Publication 1–02.

SARC. The single point of contact at an installation or within a geographic area who oversees sexual assault awareness, prevention, and response training; coordinates medical treatment, including emergency care, for victims of sexual assault; and tracks the services provided to a victim of sexual assault from the initial report through final disposition and resolution. This term and its definition are proposed for inclusion in the next edition of Joint Publication 1–02.

Senior commander. An officer, usually in the grade of O–6 or higher, who is the commander of a military installation or comparable unit and has been designated by the Military Service concerned to oversee the SAPR Program.

Service member. An active duty member of a Military Service. In addition, National Guard and Reserve Component members who are sexually assaulted when performing active service, as defined in section 101(d)(3) of Title 10, U.S.C., and inactive duty training.

Sexual assault. Intentional sexual contact characterized by use of force, threats, intimidation, or abuse of authority or when the victim does not or cannot consent. The term includes a broad category of sexual offenses consisting of the following specific UCMJ offenses: rape, sexual assault, aggravated sexual contact, abusive sexual contact, forcible sodomy (forced oral or anal sex) or attempts to commit these acts.

Unrestricted Reporting. A process that an individual covered by this policy uses to disclose, without requesting confidentiality or Restricted Reporting, that he or she is the victim of a sexual assault. Under these circumstances, the victim's report provided to healthcare personnel, the SARC, a SAPR VA, command authorities, or other persons is reported to law enforcement and may be used to initiate the official investigative process. Additional policy and guidance are provided in DoDI 6495.02. This term and its definition are proposed for inclusion in the next edition of Joint Publication 1–02.

Victim. A person who asserts direct physical, emotional, or pecuniary harm as a result of the commission of a sexual assault. The term encompasses all persons 18 and over eligible to receive treatment in military medical treatment facilities; however, the Restricted Reporting Program applies to Service Members and their military dependents 18 years of age and older. For additional persons who may be entitled to Restricted Reporting, see eligibility criteria in DoDI 6495.02.

§ 103.4 Policy.

It is DoD policy that:

(a) This part and DoDI 6495.02 implement the DoD SAPR policy.

(b) The DoD goal is a culture free of sexual assault by providing an environment of prevention, education and training, response capability (defined in DoDI 6495.02), victim support, reporting procedures, and accountability that enhances the safety and well being of all persons covered by this part and DoDI 6495.02.

(c) The SAPR Program shall:

(1) Focus on the victim and on doing what is necessary and appropriate to support victim recovery, and also, if a Service member, to support that Service member to be fully mission capable and engaged. The SAPR Program shall provide care that is gender-responsive, culturally-competent, and recovery-oriented. (See § 103.3 of this part)

(2) Not provide policy for legal processes within the responsibility of the Judge Advocates General of the Military Departments provided in Chapter 47 of Title 10, U.S.C. (also known as and hereafter referred to as ''UCMJ'') and the Manual for Court's-Martial or for criminal investigative matters assigned to the Judge Advocates General of the Military Departments and IG, DoD.

(d) Standardized SAPR requirements, terminology, guidelines, protocols, and guidelines for instructional materials shall focus on awareness, prevention, and response at all levels as appropriate.

(e) The terms ''Sexual Assault Response Coordinator (SARC)'' and ''SAPR Victim Advocate (VA),'' as defined in this part and the DoDI 6495.02, shall be used as standard terms throughout the DoD to facilitate communications and transparency regarding SAPR capacity. For further information regarding SARC and SAPR VA roles and responsibilities, see DoDI 6495.02.

(1) SARC. The SARC shall serve as the single point of contact for coordinating appropriate and responsive care for sexual assault victims. SARCs shall coordinate sexual assault victim care and sexual assault response when a sexual assault is reported. The SARC shall supervise SAPR VAs, but may be called on to perform victim advocacy duties.

(2) SAPR VA. The SAPR VA shall provide non-clinical crisis intervention and on-going support, in addition to referrals for adult sexual assault victims. Support will include providing information on available options and resources to victims.

(f) Command sexual assault awareness and prevention programs, as well as law enforcement and criminal justice procedures that enable persons to be held accountable for their actions, as appropriate, shall be established and supported by all commanders.

(g) An immediate, trained sexual assault response capability (defined in DoDI 6495.02) shall be available for each report of sexual assault in all locations, including in deployed locations. The response time may be affected by operational necessities, but will reflect that sexual assault victims shall be treated as emergency cases.

(h) Victims of sexual assault shall be protected from coercion, retaliation, and reprisal in accordance with DoDD 7050.06.

(i) Victims of sexual assault shall be protected, treated with dignity and respect, and shall receive timely access to comprehensive medical treatment, including emergency care treatment and services, as described in this part and DoDI 6495.02.

(j) Emergency care shall consist of emergency medical care and the offer of a SAFE consistent with the ''A National Protocol for Sexual Assault Medical Forensic Examinations, Adults/Adolescents'' and refer to DD Form 2911, ''DoD Sexual Assault Medical Forensic Examination Report'' and accompanying instructions. The victim shall be advised that even if a SAFE is declined, the victim is encouraged (but not mandated) to receive medical care, psychological care, and victim advocacy.

(1) Sexual assault patients shall be given priority, so that they shall be treated as emergency cases. A sexual assault victim needs immediate medical intervention to prevent loss of life or suffering resulting from physical injuries (internal or external), sexually transmitted infections, pregnancy, and psychological distress. Individuals disclosing a recent sexual assault shall, with their consent, be quickly transported to the exam site, promptly evaluated, treated for serious injuries, and then, with the patient's consent, undergo a SAFE, pursuant to ''Victim Centered Care'' of ''A National Protocol for Sexual Assault Medical Forensic Examinations, Adults/Adolescents'' and

refer to DD Form 2911 and accompanying instructions.

(2) Sexual assault patients shall be treated as emergency cases, regardless of whether physical injuries are evident. Patients' needs shall be assessed for immediate medical or mental health intervention pursuant to ''Victim Centered Care,'' and ''Triage and Intake'' of ''A National Protocol for Sexual Assault Medical Forensic Examinations, Adults/Adolescents.'' Sexual assault victims shall be treated uniformly, consistent with ''Victim Centered Care'' of ''A National Protocol for Sexual Assault Medical Forensic Examinations, Adults/Adolescents'' and DD Form 2911 and accompanying instructions, regardless of their behavior because when severely traumatized, sexual assault patients may appear to be calm, indifferent, submissive, jocular, angry, emotionally distraught, or even uncooperative or hostile towards those who are trying to help.

(k) Service members and their dependents who are 18 years of age or older covered by this part (see § 103.2(d)) and DoDI 6495.02 who are sexually assaulted have two reporting options: Unrestricted or Restricted Reporting. Complete, Unrestricted Reporting of sexual assault is favored by the DoD. See DoDI 6495.02 for additional information on the DoD sexual assault reporting options and exceptions as they apply to Restricted Reporting. Consult DoDD 5400.11 and DoD 6025.18–R for protections of personally identifiable information solicited, collected, maintained, accessed, used, disclosed, and disposed during the treatment and reporting processes. The two reporting options are as follows:

(1) Unrestricted Reporting allows an eligible person who is sexually assaulted to access medical treatment and counseling and request an official investigation of the allegation using existing reporting channels (e.g., chain of command, law enforcement, healthcare personnel, the SARC). When a sexual assault is reported through Unrestricted Reporting, a SARC shall be notified as soon as possible, respond, assign a SAPR VA, and offer the victim medical care and a SAFE.

(2) Restricted Reporting allows sexual assault victims (see eligibility criteria in § 103.2(c) of this part) to confidentially disclose the assault to specified individuals (i.e., SARC, SAPR VA, or healthcare personnel), in accordance with DoDD 5400.11, and receive medical treatment, including emergency care, counseling, and assignment of a SARC and SAPR VA, without triggering an official investigation. The victim's report to healthcare personnel (including the information acquired from a SAFE Kit), SARCs, or SAPR VAs will not be reported to law enforcement or to the victim's command, to initiate the official investigative process, unless the victim consents or an established exception applies in accordance with DoDI 6495.02. When a sexual assault is reported through Restricted Reporting, a SARC shall be notified as soon as possible, respond, assign a SAPR VA, and offer the victim medical care and a SAFE.

(i) Eligibility for Restricted Reporting. The Restricted Reporting Program applies to Service Members and their military dependents 18 years of age and older. For additional persons who may be entitled to Restricted Reporting, see eligibility criteria in DoDI 6495.02.

(ii) DoD Dual Objectives. The DoD is committed to ensuring victims of sexual assault are protected; treated with dignity and respect; and provided support, advocacy, and care. The DoD supports effective command awareness and preventive programs. The DoD also strongly supports applicable law enforcement and criminal justice procedures that enable persons to be held accountable for sexual assault offenses and criminal dispositions, as appropriate. To achieve these dual objectives, DoD preference is for complete Unrestricted Reporting of sexual assaults to allow for the provision of victims' services and to pursue accountability. However, Unrestricted Reporting may represent a barrier for victims to access services, when the victim desires no command or law enforcement involvement. Consequently, the Department recognizes a fundamental need to provide a confidential disclosure vehicle via the Restricted Reporting option.

(iii) Designated Personnel Authorized to Accept a Restricted Report. Only the SARC, SAPR VA, or healthcare personnel are designated as authorized to accept a Restricted Report.

(iv) SAFE Confidentiality Under Restricted Reporting. A SAFE and its information shall be afforded the same confidentiality as is afforded victim statements under the Restricted Reporting option. See DoDI 6495.02 for additional information.

(v) Disclosure of Confidential Communications. In cases where a victim elects Restricted Reporting, the SARC, assigned SAPR VA, and healthcare personnel may not disclose confidential communications or SAFE Kit information to law enforcement or command authorities, either within or outside the DoD, except as provided in DoDI 6495.02. In certain situations when information about a sexual assault comes to the commander's or law enforcement official's attention from a source independent of the Restricted Reporting avenues and an independent investigation is initiated, a SARC, SAPR VA, or healthcare personnel may not disclose confidential communications if obtained under Restricted Reporting (see exceptions to Restricted Reporting in DoDI 6495.02). Improper disclosure of confidential communications under Restricted Reporting, improper release of medical information, and other violations of this part are prohibited and may result in discipline pursuant to the UCMJ, or other adverse personnel or administrative actions.

(l) Enlistment or commissioning of personnel in the Military Services shall be prohibited and no waivers allowed when the person has a qualifying conviction (see § 103.3) for a crime of sexual assault.

(m) The focus of this part and DoDI 6495.02 is on the victim of sexual assault. The DoD shall provide support to an active duty Service member regardless of when or where the sexual assault took place.

§ 103.5 Responsibilities.

(a) In accordance with the authority in DoDD 5124.02, the USD(P&R) shall:

(1) Develop overall policy and provide oversight for the DoD SAPR Program, except legal processes in the UCMJ and criminal investigative matters assigned to the Judge Advocates General of the Military Departments and IG, DoD respectively.

(2) Develop strategic program guidance, joint planning objectives, standard terminology, and identify legislative changes needed to ensure the future availability of resources in support of DoD SAPR policies.

(3) Develop metrics to measure compliance and effectiveness of SAPR training, awareness, prevention, and response policies and programs. Analyze data and make recommendations regarding the SAPR policies and programs to the Secretaries of the Military Departments.

(4) Monitor compliance with this part and DoDI 6495.02, and coordinate with the Secretaries of the Military Departments regarding Service SAPR policies.

(5) Collaborate with Federal and State agencies that address SAPR issues and serve as liaison to them as appropriate. Strengthen collaboration on sexual assault policy matters with U.S. Department of Veterans Affairs on the issues of providing high quality and

accessible health care and benefits to victims of sexual assault.

(6) Oversee the DoD SAPRO. Serving as the DoD single point of authority, accountability, and oversight for the SAPR program, SAPRO provides recommendations to the USD(P&R) on the issue of DoD sexual assault policy matters on prevention, response, and oversight. SAPRO is responsible for:

(i) Implementing and monitoring compliance with DoD sexual assault policy on prevention and response, except for legal processes in the UCMJ and Manual for Courts-Martial and criminal investigative matters assigned to the Judge Advocates General of the Military Departments and IG respectively.

(ii) Providing technical assistance to the Heads of the DoD Components in addressing matters concerning SAPR.

(iii) Acquiring quarterly and annual SAPR data from the Military Services, assembling annual congressional reports involving persons covered by this part and DoDI 6495.0, and consult with and relying on the Judge Advocates General of the Military Departments in questions concerning disposition results of sexual assault cases in their respective departments.

(iv) Establishing reporting categories and monitoring specific goals included in the annual SAPR assessments of each Military Service, in their respective departments.

(v) Overseeing the creation, implementation, maintenance, and function of DSAID, an integrated database that will meet congressional reporting requirements, support Service SAPR Program management, and inform DoD SAPRO oversight activities.

(b) The Assistant Secretary of Defense for Health Affairs (ASD(HA)), under the authority, direction, and control of the USD(P&R), shall advise the USD(P&R) on DoD sexual assault healthcare policies, clinical practice guidelines, related procedures, and standards governing DoD healthcare programs for victims of sexual assault. The ASD(HA) shall direct that all sexual assault patients be given priority, so that they shall be treated as emergency cases.

(c) The Director of the Defense Human Resources Activity (DoDHRA), under the authority, direction, and control of USD(P&R), shall provide operational support to the USD(P&R) as outlined in paragraph (a)(6) of this section.

(d) The General Counsel of the DoD (GC, DoD), shall provide legal advice and assistance on all legal matters, including the review and coordination of all proposed issuances and exceptions to policy and the review of all legislative proposals affecting mission and responsibilities of the DoD SAPRO.

(e) The IG, DoD, shall:

(1) Develop and oversee the promulgation of criminal investigative and law enforcement policy regarding sexual assault and establish guidelines for the collection and preservation of evidence with non-identifiable personal information on the victim, for the Restricted Reporting process, in coordination with the ASD(HA).

(2) Oversee criminal investigations of sexual assault conducted by the DoD Components.

(3) Collaborate with the DoD SAPRO on sexual assault matters in the development of investigative policy in support of sexual assault prevention and response.

(f) The Secretaries of the Military Departments shall:

(1) Establish departmental policies and procedures to implement the SAPR Program consistent with the provisions of this part and DoDI 6495.02, to include the Military Academies within their cognizance; monitor departmental compliance with this part and DoDI 6495.02.

(2) Coordinate all Military Service SAPR policy changes with the USD(P&R).

(3) In coordination with USD(P&R), implement recommendations regarding Military Service compliance and effectiveness of SAPR training, awareness, prevention, and response policies and programs.

(4) Align Service SAPR Strategic Plans with the DoD SAPR Strategic Plan.

(5) Align Service prevention strategy with the Spectrum of Prevention, consistent with the DoD Sexual Assault Prevention Strategy, which consists of six pillars:

(i) Influencing Policy

(ii) Changing Organizational Practices

(iii) Fostering Coalitions and Networks

(iv) Educating Providers

(v) Promoting Community Education

(vi) Strengthening Individual Knowledge and Skills

(6) Require commanders to ensure that medical treatment (including emergency care) and SAPR services are provided to victims of sexual assaults in a timely manner unless declined by the victim.

(7) Utilize the terms ''Sexual Assault Response Coordinator (SARC)'' and ''SAPR Victim Advocate (VA),'' as defined in this part and DoDI 6495.02, as standard terms to facilitate communications and transparency regarding sexual assault response capacity.

(8) Establish the position of the SARC to serve as the single point of contact for ensuring that sexual assault victims receive appropriate and responsive care. The SARC should be a Service member, DoD civilian employee, or National Guard technician.

(9) Provide program-appropriate resources to enable the Combatant Commanders to achieve compliance with the policies set forth in this part and DoDI 6495.02.

(10) Establish and codify Service SAPR Program support to Combatant Commands and Defense Agencies, either as a host activity or in a deployed environment.

(11) Provide SAPR Program and obligation data to the USD(P&R), as required.

(12) Submit quarterly reports to the USD(P&R) that include information regarding all sexual assaults reported during the quarter, until DSAID becomes fully operational for each individual Service. Require confirmation that a multi-disciplinary case management group tracks each open Unrestricted Report and that a multi-disciplinary case management group meetings are held monthly for reviewing all Unrestricted Reports of sexual assaults.

(13) Provide annual reports of sexual assaults involving persons covered by this part and DoDI 6495.02 to the DoD SAPRO for consolidation into the annual report to Congress in accordance with sections 577 of Public Law 108–375.

(14) Provide data connectivity, or other means, to authorized users to ensure all sexual assaults reported in theater and other joint environments are incorporated into the DSAID, or authorized interfacing systems for the documentation of reports of sexual assault, as required by section 563 of Public Law 110–417.

(15) Ensure that Service data systems used to report case-level sexual assault information into the DSAID are compliant with DoD data reporting requirements, pursuant to section 563 of Public Law 110–417.

(16) Require extensive, continuing in-depth SAPR training for DoD personnel and specialized SAPR training for commanders, senior enlisted leaders, SARCs, SAPR VAs, investigators, law enforcement officials, chaplains, healthcare personnel, and legal personnel in accordance with DoDI 6495.02.

(17) Oversee sexual assault training within the DoD law enforcement community.

(18) Direct that Service military criminal investigative organizations

require their investigative units to communicate with their servicing SARC and participate with the multi-disciplinary Case Management Group convened by the SARC, in accordance with this part and DoDI 6495.02.

(19) Provide commanders with procedures that:

(i) Establish guidance for when a Military Protective Order (MPO) has been issued, that the Service member who is protected by the order is informed, in a timely manner, of the member's option to request transfer from the command to which that member is assigned in accordance with section 567(c) of Public Law 111–84.

(ii) Ensure that the appropriate civilian authorities shall be notified of the issuance of an military protective order (MPO) and of the individuals involved in the order, when an MPO has been issued against a Service member or when any individual addressed in the MPO does not reside on a military installation at any time when an MPO is in effect. An MPO issued by a military commander shall remain in effect until such time as the commander terminates the order or issues a replacement order. (See section 561 of Pub. L.110–417.) The issuing commander also shall notify the appropriate civilian authorities of any change made in a protective order covered by Chapter 80 of Title 10, U.S.C., and the termination of the protective order.

(iii) Ensure that the person seeking the MPO shall be advised that the MPO is not enforceable by civilian authorities off base and that victims desiring protection off base are advised to seek a civilian protective order (see section 561 of 110–417 and section 567(c) of Pub. L. 111–84).

(g) The Chairman of the Joint Chiefs of Staff shall:

(1) Assess SAPR as part of the overall force planning function of any force deployment decision, and periodically reassess the SAPR posture of deployed forces.

(2) Monitor implementation of this part, DoDI 6495.02, and implementing instructions, including during military operations.

(3) Utilize the terms ''Sexual Assault Response Coordinator (SARC)'' and ''SAPR Victim Advocate (VA),'' as defined in this part and DoDI 6495.02, as standard terms to facilitate communications and transparency regarding sexual assault response capacity.

(4) Review relevant documents, including the Combatant Commanders' joint plans, operational plans, concept plans, and deployment orders, to ensure they identify and include SAPR Program requirements.

(h) The Commanders of the Combatant Commands, in coordination with the other Heads of the DoD Components and through the Chairman of the Joint Chiefs of Staff, shall:

(1) Establish policies and procedures to implement the SAPR Program and oversee compliance with this part and DoDI 6495.02 within their areas of responsibility and during military operations.

(2) Formally document agreements with installation host Service commanders, component theater commanders, or other heads of another agency or organization, for investigative, legal, medical, counseling, or other response support provided to incidents of sexual assault.

(3) Direct that relevant documents are drafted, including joint operational plans and deployment orders, that establish theater-level requirements for the prevention of and response to incidents of sexual assault that occur, to include during the time of military operations.

(4) Require that sexual assault response capability information be provided to all persons within their area of responsibility covered by this part and DoDI 6495.02, to include reporting options and SAPR services available at deployed locations and how to access these options.

(5) Ensure medical treatment (including emergency care) and SAPR services are provided to victims of sexual assaults in a timely manner unless declined by the victim.

(6) Direct subordinate commanders coordinate relationships and agreements for host or installation support at forward-deployed locations to ensure a sexual assault response capability is available to members of their command and persons covered by this part and DoDI 6495.02 as consistent with operational requirements.

(7) Direct that sexual assault incidents are given priority so that they shall be treated as emergency cases.

(8) Direct subordinate commanders provide all personnel with procedures to report sexual assaults.

(9) Require subordinate commanders at all levels to monitor the command climate with respect to SAPR, and take appropriate steps to address problems.

(10) Require that SAPR training for DoD personnel and specialized training for commanders, senior enlisted leaders, SARCs, SAPR VAs, investigators, law enforcement officials, chaplains, healthcare personnel, and legal personnel be conducted prior to deployment in accordance with DoDI 6495.02.

(11) Direct subordinate commanders to develop procedures that:

(i) Establish guidance for when an MPO has been issued, that the Service member who is protected by the order is informed, in a timely manner, of the member's option to request transfer from the command to which that member is assigned in accordance with section 567(c) of Public Law 111–84.

(ii) In OCONUS areas, if appropriate, direct that the appropriate civilian authorities be notified of the issuance of an MPO and of the individuals involved in an order when an MPO has been issued against a Service member or when any individual involved in the MPO does not reside on a military installation when an MPO is in effect. An MPO issued by a military commander shall remain in effect until such time as the commander terminates the order or issues a replacement order. (See section 561 of Pub. L. 110–417.) The issuing commander also shall notify the appropriate civilian authorities of any change made in a protective order covered by Chapter 80 of Title 10, U.S.C. and the termination of the protective order.

(iii) Ensure that the person seeking the MPO is advised that the MPO is not enforceable by civilian authorities off base and victims desiring protection off base should be advised to seek a civilian protective order in that jurisdiction pursuant to section 562 of Public Law 110–417.

(i) The Director, DoDHRA, shall provide operational support to the USD(P&R) as outlined in paragraph (a)(6) of this section.

Dated: March 18, 2013.

Patricia L. Toppings,

OSD Federal Register Liaison, Department of Defense.

[FR Doc. 2013–07803 Filed 4–4–13; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2013–0063]

RIN 1625–AA09

Drawbridge Operation Regulations; Pelican Island Causeway, Galveston, Channel, TX

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is temporarily changing the operating schedule that governs the Pelican Island Causeway bridge across Galveston Channel mile 4.5 (GIWW mile 356.1), at Galveston, Texas. The temporary change to the regulations will allow the bridge to remain closed to navigation while major repairs are conducted to the mechanical portions of the bascule span. Failure to complete the repairs in a timely manner may render the bridge completely inoperable for the passage of vessel traffic.

DATES: This temporary final rule is effective from May 6, 2013, until July 8, 2014.

ADDRESSES: Documents mentioned in this preamble are part of docket USCG–2013–0063. To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rulemaking. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call or email David Frank, Bridge Administration Branch, Coast Guard; telephone 504–671–2128, email *David.M.Frank@uscg.mil.* If you have questions on viewing the docket, call Barbara Hairston, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of Proposed Rulemaking
§ Section Symbol
U.S.C. United States Code

A. Regulatory History and Information

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule. Publishing an NRPM is impracticable because the severity of damage and subsequent repairs necessary for this bridge were not known until recently. In this case because the scheduled repair work involved requires the bridge to be closed to navigation throughout the repair period, failure to allow the repair work to proceed as expeditiously as possible may render the bridge inoperable due to a catastrophic failure of the machinery that opens and closes the bridge. If this were to occur, the bridge would have to be closed for a much longer period of time while the machinery failures are repaired. Further, while this closure will prevent certain vessels from passing under the bridge, vessels will be able to transit an alternate route around the island through the Galveston Channel, an additional distance of up to three miles.

B. Basis and Purpose

The Pelican Island Causeway bridge, Galveston Channel mile 4.5 (GIWW mile 356.1), at Galveston, Texas, is a bascule bridge connecting Galveston Island with Pelican Island in Galveston, Texas. The roadway is the only land route between the two islands and is a vital link to numerous facilities and to the Texas A&M University Galveston Maritime School. A recent inspection by the Texas Department of Transportation and the Federal Highway Administration has determined that the ''rocker segmental girder tracks'' that allow the bridge to open and close are severely damaged and in need of immediate repair. Due to the advanced age of the bridge, replacement parts are unavailable and the existing parts will have to be removed and molds will have to be made to manufacture replacement parts.

Presently, in accordance with 33 CFR 117.966, the draw of the Pelican Island Causeway bridge across Galveston Channel, mile 4.5 of the Galveston Channel, (GIWW mile 356.1) at Galveston, Texas, shall open on signal; except that, from 6:40 a.m. to 8:10 a.m., 12 noon to 1 p.m., and 4:15 p.m. to 5:15 p.m. Monday through Friday except Federal holidays, the draw need not be opened for passage of vessels. Public vessels of the United States and vessels in distress shall be passed at any time.

Vessel traffic consists of mainly small tows and supply vessels, recreational boats and some commercial shrimpers. The bridge opens approximately 7 times per day for the passage of vessels. The vertical clearance of the bridge in the closed to navigation position is 13 feet above mean high water.

Approximately 4000 vehicles cross the bridge in each direction daily. This includes students, factory and shipyard workers and delivery vehicles of all types.

Failure to complete the repairs in a timely manner may cause a catastrophic failure of the bridge requiring a longer closure of the bridge to effect repairs. Presently, TXDOT has issued a contract for the repairs and the contractor is set to begin on May 6, 2013. The Corps of Engineers, the Port of Galveston, waterway users and the Coast Guard discussed the need for the closure with the bridge owner, TXDOT, FHWA, and the contractor to discuss ways to minimize the effects on navigation and understand the need for the work. These parties also acknowledge the fact that marine traffic can transit around the island through the Galveston Channel, an additional distance of up to three miles, with little or no interruption to their services.

C. Discussion of Temporary Final Rule

The temporary final rule will allow the bridge to be left in the closed-to-navigation position and jacked up to facilitate the removal of the rocker segmental girder track for repair/replacement of the damaged parts of the track. Removal of the track renders the bridge inoperable with regards to opening for the passage of vessels. This rule is effective from 6 a.m. on May 6, 2013, until 6 a.m. on July 8, 2014.

D. Regulatory Analyses

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

1. Regulatory Planning and Review

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

This rule is not a significant regulatory action because it has been coordinated with those parties affected by the closure and it is understood that the work is necessary for the continued operation of the bridge and by allowing it to happen in a timely manner, it

further reduces the possibility of catastrophic failure of the movable bridge. Additionally, this closure will not significantly impact navigation in the area as marine traffic may transit around the island through the Galveston Channel, an additional distance of up to three miles.

2. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended, requires federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant impact on a substantial number of small entities.

This rule would affect the following entities, some of which may be small entities: The owners or operators of vessels with vertical clearance requirements of greater than 13 feet intending to transit beneath the bridge from 6 a.m. on May 6, 2013, until 6 a.m. on July 8, 2014.

This rule will not have a significant economic impact on a substantial number of small entities for the following reasons: The bridge closure will prevent certain vessels from transiting beneath it; however, those vessels may safely transit around the island through the Galveston Channel, an additional distance of up to three miles.

3. Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT**, above.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

4. Collection of Information

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

5. Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this proposed rule under that Order and have determined that it does not have implications for federalism.

6. Protest Activities

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

7. Unfunded Mandates Reform Act

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

8. Taking of Private Property

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

9. Civil Justice Reform

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

10. Protection of Children

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

11. Indian Tribal Governments

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

12. Energy Effects

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

13. Technical Standards

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

14. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA)(42 U.S.C. 4321–4370f), and have concluded that this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This rule involves allowing a movable bridge to remain closed to navigation for 14 months and will not have any impact on the environment. This rule is categorically excluded, under figure 2–1, paragraph (32)(e), of the Instruction.

Under figure 2–1, paragraph (32)(e), of the Instruction, an environmental analysis checklist and a categorical exclusion determination are not required for this rule.

List of Subjects in 33 CFR Part 117

Bridges.

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

PART 117—DRAWBRIDGE OPERATION REGULATIONS

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

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

■ 2. Effective 6 a.m. on May 6, 2013, until 6 a.m. on July 8, 2014, suspend § 117.966.

■ 3. Add § 117.T966 to read as follows:

§ 117.T966 Pelican Island Causeway, Galveston Channel

The draw of the Pelican Island Causeway bridge across Galveston Channel, mile 4.5 of the Galveston Channel, (GIWW mile 356.1) at Galveston, Texas, need not open for the passage of vessels. This rule is effective from 6 a.m. on May 6, 2013, until 6 a.m. on July 8, 2014.

Dated: March 22, 2013.

Roy A. Nash,

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

[FR Doc. 2013–07908 Filed 4–4–13; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2013–0020]

RIN 1625–AA00

Safety Zones; Annual Events Requiring Safety Zones in the Captain of the Port Lake Michigan Zone

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is amending its regulations requiring safety zones in the Captain of the Port Lake Michigan zone. This rule will amend the rules that restrict vessels from portions of water areas during events that pose a hazard to public safety. The safety zones amended or established by this rule are necessary to protect spectators, participants, and vessels from the hazards associated with various maritime events.

DATES: This rule is effective May 6, 2013.

ADDRESSES: Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket USCG–2013–0020 and are available online at *www.regulations.gov.* This material is also available for inspection or copying at two locations: 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 and the U.S. Coast Guard Sector Lake Michigan, 2420 South Lincoln Memorial Drive, Milwaukee, WI 53207, between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, contact MST1 Joseph McCollum, Prevention Department, Coast Guard Sector Lake Michigan, Milwaukee, WI at (414) 747–7148 or by email at *Joseph.P.McCollum@USCG.mil.* If you have questions on viewing or submitting material to the docket, call Barbara Hairston, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

DHS Department of Homeland Security
FR Federal Register
NPRM Notice of Proposed Rulemaking
TFR Temporary Final Rule

A. Regulatory History and Information

On February 11, 2013, the Coast Guard published a notice of proposed rulemaking entitled Safety Zones; Annual Events Requiring Safety Zones in the Captain of the Port Lake Michigan Zone in the **Federal Register** (2013–02955). We received 4 comments on the proposed rule. All of the 4 comments received were from event organizers, detailing minor changes to the date, time, or location of the event listed in the NPRM. These comments are addressed specifically within this final rule. No public meeting was requested, and none was held.

B. Basis and Purpose

This rule will amend 33 CFR 165.929, Annual Events requiring safety zones in the Captain of the Port Lake Michigan zone. Specifically, this rule will remove 1 permanent safety zone, revise the location and/or enforcement period of 11 others, and add 3 permanent safety zones for annually recurring events.

Changes to existing safety zones in 33 CFR 165.929 correlate to changes to annual marine events for which these safety zones are established. Event organizers report changes to annual marine events to the Coast Guard, and in light of these reports, the Coast Guard adjusts the position and/or enforcement period of the established safety zones to ensure that vessels and persons are protected from the specific hazards of these marine events. Such hazards include obstructions to the waterway, collisions among spectators and event participants, and falling debris. Six of the 11 revisions to the location and/or enforcement period of safety zones concerned reported changes to annually occurring fireworks displays. Additionally, the Coast Guard was informed by one Event Organizer that a fireworks display listed in 33 CFR 165.929 would no longer take place. For this reason, the removal of its accompanying safety zone was necessary.

The Coast Guard also added three new safety zones for events that have been reported as recurring in the Lake Michigan Zone. The last three entries within this rule have been added for races in the Chicago, IL area and on Spring Lake, MI. For the reader's convenience, we have republished the revised 33 CFR 165.929 in its entirety.

C. Discussion of Comments, Changes, and the Final Rule

Four comments were received regarding the safety zones listed within the NPRM. Each comment called for a minor position or time change to what was listed in the NPRM. In support for amending the event as listed in the NPRM, the Coast Guard considered that making minor edits to the times and locations would both provide the public with the most accurate information, and protect the public from the hazards associated with each event.

The first comment received regarded 33 CFR 165.929(37). The comment was from the organizer of the event for which the safety zone was written—Celebrate Americafest/Fire over the Fox. This event has historically involved both a fireworks display and a ski show. The event organizer commented that the safety zone, as written in the NPRM, would need to be extended 1300 feet to the southwest and enforced for two hours in the early afternoon on the day of the event. To ensure the safety of the Celebrate Americafest/Fire over the Fox event in its entirety, the language of 33 CFR 165.929(37) was amended to reflect these changes. The language of 33 CFR 165.929(37) was also amended to reflect the times and locations of the safety zone for ski show and fireworks.

The second comment received regarded 33 CFR 165.929(16). The comment was from the organizer of the event for which the safety zone was written—Freedom Festival Fireworks. The event organizer commented by sending a picture to show the launch position of the fireworks; this position differed from what had been listed in the NPRM for the event. This new position was only 650 feet south of its position within the NPRM. The language of 33 CFR 165.929(16) was

amended to show the accurate position from which the fireworks would be launched.

The third comment received regarded 33 CFR 165.929(6). The comment was from the organizer of the event for which the safety zone was written—Michigan Super Boat Grand Prix. The event organizer commented that, due to scheduling concerns, the addition of a rain date was needed. Furthermore, the organizer submitted a picture of the race course. The race course extended approximately 900 feet farther to the southwest than was currently covered by the safety zone within the NPRM. The language of 33 CFR 165.929(6) was amended to allow the safety zone to accommodate for the length of the race course. An amendment was also made to include a rain date.

The fourth comment received regarded 33 CFR 165.929(22). The comment was from the organizer of the event for which the safety zone was written—Independence Day Fireworks; Saugatuck, MI. The event organizer commented that the launch site for the fireworks would take place in the middle of Kalamazoo Lake. This new launch site was approximately 1100 feet north of the position described in the NPRM. The language of 33 CFR 165.929(22) was amended so that the safety zone will accommodate the new position of the fireworks barge in the middle of Lake Kalamazoo.

D. Discussion of Rule

The safety zones in this rule are necessary to ensure the safety of vessels and people during annual marine events in the Captain of the Port Lake Michigan area of responsibility. Although this rule will remain in effect year round, the safety zones within it will be enforced only immediately before, during, and after events that pose a hazard to the public, and only upon notice by the Captain of the Port.

The Captain of the Port Lake Michigan will notify the public that the zones in this proposal are or will be enforced by all appropriate means to the affected segments of the public including publication in the **Federal Register** as practicable, in accordance with 33 CFR 165.7(a). Such means of notification may also include, but are not limited to, Broadcast Notice to Mariners or Local Notice to Mariners. The Captain of the Port will issue a Broadcast Notice to Mariners notifying the public when enforcement of the safety zone established by this section is cancelled.

All persons and vessels shall comply with the instructions of the Coast Guard Captain of the Port or the designated representative. Entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the Captain of the Port Lake Michigan, or his designated representative. The Captain of the Port or his designated representative may be contacted via VHF Channel 16.

E. Regulatory Analysis

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

1. Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not ''significant'' under the regulatory policies and procedures of the Department of Homeland Security (DHS). We conclude that this rule is not a significant regulatory action because we anticipate that it will have minimal impact on the economy, will not interfere with other agencies, will not adversely alter the budget of any grant or loan recipients, and will not raise any novel legal or policy issues. The safety zones created by this rule will be relatively small and enforced for relatively short time. Also, each safety zone is designed to minimize its impact on navigable waters. Furthermore, each safety zone has been designed to allow vessels to transit unrestricted to portions of the waterways not affected by the safety zones. Thus, restrictions on vessel movements within that particular area are expected to be minimal. Under certain conditions, moreover, vessels may still transit through each safety zone when permitted by the Captain of the Port, Sector Lake Michigan. On the whole, the Coast Guard expects insignificant adverse impact to mariners from the activation of these safety zones.

2. Small Entities

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

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule would not have a significant economic impact on a substantial number of small entities. This rule would affect the following entities, some of which might be small entities: The owners and operators of vessels intending to transit or anchor in any one of the below established safety zones while the safety zone is being enforced. These safety zones will not have a significant economic impact on a substantial number of small entities for the following reasons: Each safety zone in this rule will be in effect for only a few hours within any given 24 hour period. Each of the safety zones will be in effect only once per year. Furthermore, these safety zones have been designed to allow traffic to pass safely around each zone. Moreover, vessels will be allowed to pass through each zone at the discretion of the Captain of the Port, Sector Lake Michigan, or his or her designated representative.

On February 11, 2013, the Coast Guard published a notice of proposed rulemaking entitled Safety Zones; Annual events requiring safety zones in the Captain of the Port Lake Michigan zone in the **Federal Register** (2013–02955). The Coast Guard received 0 public submissions commenting on the impact to small entities by this rule. There have been no changes made to the rule as proposed.

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

3. Assistance for Small Entities

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

4. Collection of Information

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

5. Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and

would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

6. Unfunded Mandates Reform Act

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

7. Taking of Private Property

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

8. Civil Justice Reform

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

9. Protection of Children

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

10. Indian Tribal Governments

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

11. Energy Effects

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

12. Technical Standards

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

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

13. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. An environmental analysis checklist supporting this determination is available in the docket where indicated under **ADDRESSES**. This rule involves the establishment, disestablishment, and changing of safety zones, and thus, paragraph 34(g) of figure 2–1 in Commandant Instruction M16475.lD applies.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and record keeping requirements, Security measures, Waterways.

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

■ 2. Revise § 165.929 to read as follows:

§ 165.929 Safety Zones; Annual events requiring safety zones in the Captain of the Port Lake Michigan zone.

(a) *Safety zones.* The following are designated as safety zones:

(1) *St. Patrick's Day Fireworks; Manitowoc, WI*—

(i) *Location.* All waters of the Manitowoc River and Manitowoc Harbor, near the mouth of the Manitowoc River on the south shore, within the arc of a circle with a 100-foot radius from the fireworks launch site located in position 44°05′30″ N, 087°39′12″ W (NAD 83).

(ii) *Enforcement date and time.* The third Saturday of March; 5:30 p.m. to 7 p.m.

(2) *Michigan Aerospace Challenge Sport Rocket Launch; Muskegon, MI*—(i) *Location.* All waters of Muskegon Lake, near the West Michigan Dock and Market Corp facility, within the arc of a circle with a 1500-yard radius from the rocket launch site located in position 43°14′21″ N, 086°15′35″ W (NAD 83).

(ii) *Enforcement date and time.* The last Saturday of April; 8 a.m. to 4 p.m.

(3) *Tulip Time Festival Fireworks; Holland, MI*—(i) *Location.* All waters of Lake Macatawa, near Kollen Park, within the arc of a circle with a 1000-foot radius from the fireworks launch site in position 42°47′23″ N, 086°07′22″ W (NAD 83).

(ii) *Enforcement date and time.* The first Saturday of May; 9:30 p.m. to 11:30 p.m. If the Saturday fireworks are cancelled due to inclement weather, then this safety zone will be enforced on the first Friday of May; 9:30 p.m. to 11:30 p.m.

(4) *Rockets for Schools Rocket Launch; Sheboygan, WI*—(i) *Location.* All waters of Lake Michigan and Sheboygan Harbor, near the Sheboygan South Pier, within the arc of a circle with a 1500-yard radius from the rocket launch site located with its center in position 43°44′55″ N, 087°41′52″ W (NAD 83).

(ii) *Enforcement date and time.* The first Saturday of May; 8 a.m. to 5 p.m.

(5) *Celebrate De Pere; De Pere, WI*—(i) *Location.* All waters of the Fox River, near Voyageur Park, within the arc of a

circle with a 500 foot radius from the fireworks launch site located in position 44°27′10″ N, 088°03′50″ W (NAD 83).

(ii) *Enforcement date and time.* The Sunday before Memorial Day; 8:30 p.m. to 10 p.m.

(6) *Michigan Super Boat Grand Prix; Michigan City, IN*—(i) *Location.* All waters of Lake Michigan bounded by a rectangle drawn from 41°43′39.3″ N, 086°54′33.0″ W; then northeast to 41°44′48.5″ N, 086°51′17.6″ W, then northwest to 41°45′11.7″ N, 086°51′45.4″ W; then southwest to 41°44′3.8″ N, 086°54′52.4″ W; then southeast returning to the point of origin (NAD 83).

(ii) *Enforcement date and time.* The first Sunday of August; 9:00 a.m. to 4:00 p.m. If the Sunday Race is cancelled due to inclement weather, then this safety zone will be enforced on the first Saturday of August; 9:00 a.m. to 4:00 p.m.

(7) *International Bayfest; Green Bay, WI*—(i) *Location.* All waters of the Fox River, near the Western Lime Company 1.13 miles above the head of the Fox River, within the arc of a circle with a 1,000-foot radius from the fireworks launch site located in position 44°31′24″ N, 088°00′42″ W (NAD 83).

(ii) *Enforcement date and time.* The second Friday of June; 9 p.m. to 11 p.m.

(8) *Harborfest Music and Family Festival; Racine, WI*—(i) *Location.* All waters of Lake Michigan and Racine Harbor, near the Racine Launch Basin Entrance Light, within the arc of a circle with a 200-foot radius from the fireworks launch site located in position 42°43′43″ N, 087°46′40″ W (NAD 83).

(ii) *Enforcement date and time.* Friday and Saturday of the third complete weekend of June; 9 p.m. to 11 p.m. each day.

(9) *Spring Lake Heritage Festival Fireworks; Spring Lake, MI*—(i) *Location.* All waters of the Grand River, near buoy 14A, within the arc of a circle with a 500-foot radius from the fireworks launch site located on a barge in position 43°04′24″ N, 086°12′42″ W (NAD 83).

(ii) *Enforcement date and time.* The third Saturday of June; 9 p.m. to 11 p.m.

(10) *Elberta Solstice Festival Fireworks; Elberta, MI*—(i) *Location.* All waters of Betsie Bay, near Waterfront Park, within the arc of a circle with a 500-foot radius from the fireworks launch site located in position 44°37′43″ N, 086°14′27″ W (NAD 83).

(ii) *Enforcement date and time.* The last Saturday of June; 9 p.m. to 11 p.m.

(11) *Pentwater July Third Fireworks; Pentwater, MI*—(i) *Location.* All waters of Lake Michigan and the Pentwater Channel within the arc of a circle with a 1,000-foot radius from the fireworks launch site located in position 43°46′57″ N, 086°26′38″ W (NAD 83).

(ii) *Enforcement date and time.* July 3; 9 p.m. to 11 p.m. If the July 3 fireworks are cancelled due to inclement weather, then this safety zone will be enforced July 4; 9 p.m. to 11 p.m.

(12) *Taste of Chicago Fireworks; Chicago, IL*—(i) *Location.* All waters of Monroe Harbor and all waters of Lake Michigan bounded by a line drawn from 41°53′24″ N, 087°35′59″ W; then east to 41°53′15″ N, 087°35′26″ W; then south to 41°52′49″ N, 087°35′26″ W; then southwest to 41°52′27″ N, 087°36′37″ W; then north to 41°53′15″ N, 087°36′33″ W; then east returning to the point of origin (NAD 83).

(ii) *Enforcement date and time.* July 3; 9 p.m. to 11 p.m. If the July 3 fireworks are cancelled due to inclement weather, then this safety zone will be enforced July 4; 9 p.m. to 11 p.m.

(13) *U.S. Bank Fireworks; Milwaukee, WI*—(i) *Location.* All waters and adjacent shoreline of Milwaukee Harbor, in the vicinity of Veteran's park, within the arc of a circle with a 1,200-foot radius from the center of the fireworks launch site which is located on a barge with its approximate position located at 43°02′22″ N, 087°53′29″ W (NAD 83).

(ii) *Enforcement date and time.* July 3; 9 p.m. to 11 p.m. If the July 3 fireworks are cancelled due to inclement weather, then this safety zone will be enforced July 4; 9 p.m. to 11 p.m.

(14) *Independence Day Fireworks; Manistee, MI*—(i) *Location.* All waters of Lake Michigan, in the vicinity of the First Street Beach, within the arc of a circle with a 1,000-foot radius from the fireworks launch site located in position 44°14′51″ N, 086°20′46″ W (NAD 83).

(ii) *Enforcement date and time.* July 3; 9 p.m. to 11 p.m. If the July 3 fireworks are cancelled due to inclement weather, then this safety zone will be enforced July 4; 9 p.m. to 11 p.m.

(15) *Frankfort Independence Day Fireworks; Frankfort, MI*—(i) *Location.* All waters of Lake Michigan and Frankfort Harbor, bounded by a line drawn from 44°38′05″ N, 086°14′50″ W; then south to 44°37′39″ N, 086°14′50″ W; then west to 44°37′39″ N, 086°15′20″ W; then north to 44°38′05″ N, 086°15′20″ W; then east returning to the point of origin (NAD 83).

(ii) *Enforcement date and time.* July 4; 9 p.m. to 11 p.m. If the July 4 fireworks are cancelled due to inclement weather, then this safety zone will be enforced July 5; 9 p.m. to 11 p.m.

(16) *Freedom Festival Fireworks; Ludington, MI*—(i) *Location.* All waters of Lake Michigan and Ludington Harbor within the arc of a circle with a 800-foot radius from the fireworks launch site located in position 43°57′10.3″ N, 086°27′43.0″ W (NAD 83).

(ii) *Enforcement date and time.* July 4; 9 p.m. to 11 p.m. If the July 4 fireworks are cancelled due to inclement weather, then this safety zone will be enforced July 5; 9 p.m. to 11 p.m.

(17) *White Lake Independence Day Fireworks; Montague, MI*—(i) *Location.* All waters of White Lake, in the vicinity of the Montague boat launch, within the arc of a circle with a 1000-foot radius from the fireworks launch site located in position 43°24′33″ N, 086°21′28″ W (NAD 83).

(ii) *Enforcement date and time.* July 4; 9 p.m. to 11 p.m. If the July 4 fireworks are cancelled due to inclement weather, then this safety zone will be enforced July 5; 9 p.m. to 11 p.m.

(18) *Muskegon Summer Celebration July Fourth Fireworks; Muskegon, MI*—(i) *Location.* All waters of Muskegon Lake, in the vicinity of Heritage Landing, within the arc of a circle with a 1000-foot radius from a fireworks launch site located on a barge in position 43°14′00″ N, 086°15′50″ W (NAD 83).

(ii) *Enforcement date and time.* July 4; 9 p.m. to 11 p.m. If the July 4 fireworks are cancelled due to inclement weather, then this safety zone will be enforced July 5; 9 p.m. to 11 p.m.

(iii) Impact on Special Anchorage Area regulations: Regulations for that portion of the Muskegon Lake East Special Anchorage Area, as described in 33 CFR 110.81(b), which are overlapped by this regulation, are suspended during this event. The remaining area of the Muskegon Lake East Special Anchorage Area not impacted by this regulation remains available for anchoring during this event.

(19) *Grand Haven Jaycees Annual Fourth of July Fireworks; Grand Haven, MI*—(i) *Location.* All waters of The Grand River between longitude 087°14′00″ W, near The Sag, then west to longitude 087°15′00″ W, near the west end of the south pier (NAD 83).

(ii) *Enforcement date and time.* July 4; 9 p.m. to 11 p.m. If the July 4 fireworks are cancelled due to inclement weather, then this safety zone will be enforced July 5; 9 p.m. to 11 p.m.

(20) *Celebration Freedom Fireworks; Holland, MI*—(i) *Location.* All waters of Lake Macatawa, in the vicinity of Kollen Park, within the arc of a circle with a 1000-foot radius from the fireworks launch site located in position 42°47′23″ N, 086°07′22″ W (NAD 83).

(ii) *Enforcement date and time.* The Saturday prior to July 4; 9 p.m. to 11 p.m. If the fireworks are cancelled due to inclement weather, then this safety

zone will be enforced the Sunday prior to July 4; 9 p.m. to 11 p.m.

(21) *Van Andel Fireworks Show; Holland, MI*—(i) *Location.* All waters of Lake Michigan and the Holland Channel within the arc of a circle with a 1000-foot radius from the fireworks launch site located in position 42°46′21″ N, 086°12′48″ W (NAD 83).

(ii) *Enforcement date and time.* July 3; 9 p.m. to 11 p.m. If the July 3 fireworks are cancelled due to inclement weather, then this safety zone will be enforced July 4; 9 p.m. to 11 p.m.

(22) *Independence Day Fireworks; Saugatuck, MI*—(i) *Location.* All waters of Kalamazoo Lake within the arc of a circle with a 600-foot radius from the fireworks launch site in position 42°39′4.3″ N, 086°12′16.5″ W (NAD 83).

(ii) *Enforcement date and time.* July 4; 8 p.m. to 10 p.m. If the July 4 fireworks are cancelled due to inclement weather, then this safety zone will be enforced July 5; 8 p.m. to 10 p.m.

(23) *South Haven Fourth of July Fireworks; South Haven, MI*—(i) *Location.* All waters of Lake Michigan and the Black River within the arc of a circle with a 1000-foot radius from the fireworks launch site located in position 42°24′7.5″ N, 086°17′11.8″ W (NAD 83).

(ii) *Enforcement date and time.* July 3; 9:30 p.m. to 11:30 p.m.

(24) *St. Joseph Fourth of July Fireworks; St. Joseph, MI*—(i) *Location.* All waters of Lake Michigan and the St. Joseph River within the arc of a circle with a 1000-foot radius from the fireworks launch site located in position 42°06′48″ N, 086°29′5″ W (NAD 83).

(ii) *Enforcement date and time.* July 4; 9 p.m. to 11 p.m. If the July 4 fireworks are cancelled due to inclement weather, then this safety zone will be enforced July 5; 9 p.m. to 11 p.m.

(25) *Town of Dune Acres Independence Day Fireworks; Dune Acres, IN*—(i) *Location.* All waters of Lake Michigan within the arc of a circle with a 1000-foot radius from the fireworks launch site located in position 41°39′23″ N, 087°04′59″ W (NAD 83).

(ii) *Enforcement date and time.* The first Saturday of July; 9:00 p.m. to 11:00 p.m.

(26) *Gary Fourth of July Fireworks; Gary, IN*—(i) *Location.* All waters of Lake Michigan, approximately 2.5 miles east of Gary Harbor, within the arc of a circle with a 500-foot radius from the fireworks launch site located in position 41°37′19″ N, 087°14′31″ W (NAD 83).

(ii) *Enforcement date and time.* July 4; 9 p.m. to 11 p.m. If the July 4 fireworks are cancelled due to inclement weather, then this safety zone will be enforced July 5; 9 p.m. to 11 p.m.

(27) *Joliet Independence Day Celebration Fireworks; Joliet, IL*—(i) *Location.* All waters of the Des Plains River, at mile 288, within the arc of a circle with a 500-foot radius from the fireworks launch site located in position 41°31′31″ N, 088°05′15″ W (NAD 83).

(ii) *Enforcement date and time.* July 3; 9 p.m. to 11 p.m. If the July 3 fireworks are cancelled due to inclement weather, then this safety zone will be enforced July 4; 9 p.m. to 11 p.m.

(28) *Glencoe Fourth of July Celebration Fireworks; Glencoe, IL*—(i) *Location.* All waters of Lake Michigan, in the vicinity of Lake Front Park, within the arc of a circle with a 500-foot radius from the fireworks launch site located in position 42°08′17″ N, 087°44′55″ W (NAD 83).

(ii) *Enforcement date and time.* July 4; 9 p.m. to 11 p.m. If the July 4 fireworks are cancelled due to inclement weather, then this safety zone will be enforced July 5; 9 p.m. to 11 p.m.

(29) *Lakeshore Country Club Independence Day Fireworks; Glencoe, IL*—(i) *Location.* All waters of Lake Michigan within the arc of a circle with a 1000-foot radius from the fireworks launch site located in position 42°08′27″ N, 087°44′57″ W (NAD 83).

(ii) *Enforcement date and time.* July 4; 9 p.m. to 11 p.m. If the July 4 fireworks are cancelled due to inclement weather, then this safety zone will be enforced July 5; 9 p.m. to 11 p.m.

(30) *Shore Acres Country Club Independence Day Fireworks; Lake Bluff, IL*—(i) *Location.* All waters of Lake Michigan, approximately one mile north of Lake Bluff, IL, within the arc of a circle with a 1000-foot radius from the fireworks launch site located in position 42°17′59″ N, 087°50′03″ W (NAD 83).

(ii) *Enforcement date and time.* July 4; 9 p.m. to 11 p.m. If the July 4 fireworks are cancelled due to inclement weather, then this safety zone will be enforced July 5; 9 p.m. to 11 p.m.

(31) *Kenosha Independence Day Fireworks; Kenosha, WI*—(i) *Location.* All waters of Lake Michigan and Kenosha Harbor within the arc of a circle with a 1000-foot radius from the fireworks launch site located in position 42°35′17″ N, 087°48′27″ W (NAD 83).

(ii) *Enforcement date and time.* July 4; 9 p.m. to 11 p.m. If the July 4 fireworks are cancelled due to inclement weather, then this safety zone will be enforced July 5; 9 p.m. to 11 p.m.

(32) *Fourthfest of Greater Racine Fireworks; Racine, WI*—(i) *Location.* All waters of Lake Michigan and Racine Harbor, in the vicinity of North Beach, within the arc of a circle with a 1000-foot radius from the fireworks launch site located in position 42°44′17″ N, 087°46′42″ W (NAD 83).

(ii) *Enforcement date and time.* July 4; 9 p.m. to 11 p.m. If the July 4 fireworks are cancelled due to inclement weather, then this safety zone will be enforced July 5; 9 p.m. to 11 p.m.

(33) *Sheboygan Fourth of July Celebration Fireworks; Sheboygan, WI*—(i) *Location.* All waters of Lake Michigan and Sheboygan Harbor, in the vicinity of the south pier, within the arc of a circle with a 1000-foot radius from the fireworks launch site located in position 43°44′55″ N, 087°41′51″ W (NAD 83).

(ii) *Enforcement date and time.* July 4; 9 p.m. to 11 p.m. If the July 4 fireworks are cancelled due to inclement weather, then this safety zone will be enforced July 5; 9 p.m. to 11 p.m.

(34) *Manitowoc Independence Day Fireworks; Manitowoc, WI*—(i) *Location.* All waters of Lake Michigan and Manitowoc Harbor, in the vicinity of south breakwater, within the arc of a circle with a 1000-foot radius from the fireworks launch site located in position 44°05′24″ N, 087°38′45″ W (NAD 83).

(ii) *Enforcement date and time.* July 4; 9 p.m. to 11 p.m. If the July 4 fireworks are cancelled due to inclement weather, then this safety zone will be enforced July 5; 9 p.m. to 11 p.m.

(35) *Sturgeon Bay Independence Day Fireworks; Sturgeon Bay, WI*—(i) *Location.* All waters of Sturgeon Bay, in the vicinity of Sunset Park, within the arc of a circle with a 1000-foot radius from the fireworks launch site located on a barge in position 44°50′37″ N, 087°23′18″ W (NAD 83).

(ii) *Enforcement date and time.* July 4; 9 p.m. to 11 p.m. If the July 4 fireworks are cancelled due to inclement weather, then this safety zone will be enforced July 5; 9 p.m. to 11 p.m.

(36) *Fish Creek Independence Day Fireworks; Fish Creek, WI*—(i) *Location.* All waters of Green Bay, in the vicinity of Fish Creek Harbor, within the arc of a circle with a 1000-foot radius from the fireworks launch site located on a barge in position 45°07′52″ N, 087°14′37″ W (NAD 83).

(ii) *Enforcement date and time.* The first Saturday after July 4; 9 p.m. to 11 p.m.

(37) *Celebrate Americafest/Fire over the Fox; Green Bay, WI*—(i) *Location.* For the fireworks show: All waters of the Fox River including the mouth of the East River from the railroad bridge in approximate position 44°31′28″ N, 088°0′38″ W then southwest to the US 141 bridge in approximate position 44°31′6.1″ N, 088°0′57.8″ W (NAD 83). For the ski show: all waters of the Fox River including the mouth of the East

River from the West Walnut Street Bridge in approximate position 44°30′54.7″ N, 088°01′06″ W, then northeast to an imaginary line across the river bisecting 44°31′20.2″ N, 088°0′38.4″ W (NAD 83).

(ii) *Enforcement date and time.* July 4 from 2:30 p.m. to 4:30 p.m. for the ski show and from 9:45 p.m. to 11:00 p.m. for the fireworks display. If the July 4 events are cancelled due to inclement weather, then this safety zone will be enforced July 5; 2:30 p.m. to 4:30 p.m. for the ski show and from 9:45 p.m. to 11:00 p.m. for the fireworks display.

(38) *Marinette Fourth of July Celebration Fireworks; Marinette, WI*—(i) *Location.* All waters of the Menominee River, in the vicinity of Stephenson Island, within the arc of a circle with a 1000-foot radius from the fireworks launch site located in position 45°06′09″ N, 087°37′39″ W and all waters located between the Highway U.S. 41 bridge and the Hattie Street Dam (NAD 83).

(ii) *Enforcement date and time.* July 4; 9 p.m. to 11 p.m. If the July 4 fireworks are cancelled due to inclement weather, then this safety zone will be enforced July 5; 9 p.m. to 11 p.m.

(39) *Evanston Fourth of July Fireworks; Evanston, IL*—(i) *Location.* All waters of Lake Michigan, in the vicinity of Centennial Park Beach, within the arc of a circle with a 500-foot radius from the fireworks launch site located in position 42°02′56″ N, 087°40′21″ W (NAD 83).

(ii) *Enforcement date and time.* July 4; 9 p.m. to 11 p.m. If the July 4 fireworks are cancelled due to inclement weather, then this safety zone will be enforced July 5; 9 p.m. to 11 p.m.

(40) *Muskegon Summer Celebration Fireworks; Muskegon, MI*—(i) *Location.* All waters of Muskegon Lake, in the vicinity of Heritage Landing, within the arc of a circle with a 1000-foot radius from a fireworks barge located in position 43°14′00″ N, 086°15′50″ W (NAD 83).

(ii) *Enforcement date and time.* The Sunday following July 4; 9 p.m. to 11 p.m.

(iii) Impact on Special Anchorage Area regulations: Regulations for that portion of the Muskegon Lake East Special Anchorage Area, as described in 33 CFR 110.81(b), which are overlapped by this regulation, are suspended during this event. The remaining area of the Muskegon Lake East Special Anchorage Area is not impacted by this regulation and remains available for anchoring during this event.

(41) *Gary Air and Water Show; Gary, IN*—(i) *Location.* All waters of Lake Michigan bounded by a line drawn from 41°37′42″ N, 087°16′38″ W; then east to 41°37′54″ N, 087°14′00″ W; then south to 41°37′30″ N, 087°13′56″ W; then west to 41°37′17″ N, 087°16′36″ W; then north returning to the point of origin (NAD 83).

(ii) *Enforcement date and time.* This event has historically occurred during the month of July. The Captain of the Port, Sector Lake Michigan, will establish enforcement dates that will be announced with a Notice of Enforcement and marine information broadcasts.

(42) *Milwaukee Air and Water Show; Milwaukee, WI*—(i) *Location.* All waters and adjacent shoreline of Lake Michigan and Bradford Beach located within an area that is approximately 4600 by 1550 yards. The area will be bounded by the points beginning at 43°02′57″ N, 087°52′50″ W; then south along the Milwaukee Harbor break wall to 43°02′41″ N, 087°52′49″ W; then southeast to 43°02′26″ N, 087°52′01″ W; then northeast to 43°04′27″ N, 087°50′30″ W; then northwest to 43°04′41″ N, 087°51′29″ W; then southwest returning to the point of origin (NAD 83).

(ii) *Enforcement date and time.* This event has historically occurred during the month of August. The Captain of the Port, Sector Lake Michigan, will establish enforcement dates that will be announced with a Notice of Enforcement and marine information broadcasts.

(43) *Annual Trout Festival Fireworks; Kewaunee, WI*—(i) *Location.* All waters of Kewaunee Harbor and Lake Michigan within the arc of a circle with a 1000-foot radius from the fireworks launch site located in position 44°27′29″ N, 087°29′45″ W (NAD 83).

(ii) *Enforcement date and time.* Friday of the second complete weekend of July; 9 p.m. to 11 p.m.

(44) *Michigan City Summerfest Fireworks; Michigan City, IN*—(i) *Location.* All waters of Michigan City Harbor and Lake Michigan within the arc of a circle with a 1000-foot radius from the fireworks launch site located in position 41°43′42″ N, 086°54′37″ W (NAD 83).

(ii) *Enforcement date and time.* Sunday of the first complete weekend of July; 9 p.m. to 11 p.m.

(45) *Port Washington Fish Day Fireworks; Port Washington, WI*—(i) *Location.* All waters of Port Washington Harbor and Lake Michigan, in the vicinity of the WE Energies coal dock, within the arc of a circle with a 1000-foot radius from the fireworks launch site located in position 43°23′07″ N, 087°51′54″ W (NAD 83).

(ii) *Enforcement date and time.* The third Saturday of July; 9 p.m. to 11 p.m.

(46) *Bay View Lions Club South Shore Frolics Fireworks; Milwaukee, WI*—(i) *Location.* All waters of Milwaukee Harbor and Lake Michigan, in the vicinity of South Shore Park, within the arc of a circle with a 500-foot radius from the fireworks launch site in position 42°59′42″ N, 087°52′52″ W (NAD 83).

(ii) *Enforcement date and time.* Friday, Saturday, and Sunday of the second or third weekend of July; 9 p.m. to 11 p.m. each day.

(47) *Venetian Festival Fireworks; St. Joseph, MI*—(i) *Location.* All waters of Lake Michigan and the St. Joseph River, near the east end of the south pier, within the arc of a circle with a 1000-foot radius from the fireworks launch site located in position 42°06′48″ N, 086°29′15″ W (NAD 83).

(ii) *Enforcement date and time.* Saturday of the third complete weekend of July; 9 p.m. to 11 p.m.

(48) *Joliet Waterway Daze Fireworks; Joliet, IL*—(i) *Location.* All waters of the Des Plaines River, at mile 287.5, within the arc of a circle with a 300-foot radius from the fireworks launch site located in position 41°31′15″ N, 088°05′17″ W (NAD 83).

(ii) *Enforcement date and time.* Friday and Saturday of the third complete weekend of July; 9 p.m. to 11 p.m. each day.

(49) *EAA Airventure; Oshkosh, WI*—(i) *Location.* All waters of Lake Winnebago bounded by a line drawn from 43°57′30″ N, 088°30′00″ W; then south to 43°56′56″ N, 088°29′53″ W, then east to 43°56′40″ N, 088°28′40″ W; then north to 43°57′30″ N, 088°28′40″ W; then west returning to the point of origin (NAD 83).

(ii) *Enforcement date and time.* The last complete week of July, beginning Monday and ending Sunday; from 8 a.m. to 8 p.m. each day.

(50) *Venetian Night Fireworks; Saugatuck, MI*—(i) *Location.* All waters of Kalamazoo Lake within the arc of a circle with a 500-foot radius from the fireworks launch site located on a barge in position 42°38′52″ N, 086°12′18″ W (NAD 83).

(ii) *Enforcement date and time.* The last Saturday of July; 9 p.m. to 11 p.m.

(51) *Roma Lodge Italian Festival Fireworks; Racine, WI*—(i) *Location.* All waters of Lake Michigan and Racine Harbor within the arc of a circle with a 1000-foot radius from the fireworks launch site located in position 42°44′04″ N, 087°46′20″ W (NAD 83).

(ii) *Enforcement date and time.* Friday and Saturday of the last complete weekend of July; 9 p.m. to 11 p.m.

(52) *Venetian Night Fireworks; Chicago, IL*—(i) *Location.* All waters of Monroe Harbor and all waters of Lake Michigan bounded by a line drawn from 41°53′03″ N, 087°36′36″ W; then east to 41°53′03″ N, 087°36′21″ W; then south to 41°52′27″ N, 087°36′21″ W; then west to 41°52′27″ N, 087°36′37″ W; then north returning to the point of origin (NAD 83).

(ii) *Enforcement date and time.* Saturday of the last weekend of July; 9 p.m. to 11 p.m.

(53) *Port Washington Maritime Heritage Festival Fireworks; Port Washington, WI*—(i) *Location.* All waters of Port Washington Harbor and Lake Michigan, in the vicinity of the WE Energies coal dock, within the arc of a circle with a 1000-foot radius from the fireworks launch site located in position 43°23′07″ N, 087°51′54″ W (NAD 83).

(ii) *Enforcement date and time.* Saturday of the last complete weekend of July or the second weekend of August; 9 p.m. to 11 p.m.

(54) *Grand Haven Coast Guard Festival Fireworks; Grand Haven, MI*—(i) *Location.* All waters of the Grand River within the arc of a circle with a 600-foot radius from the fireworks launch site located on the west bank of the Grand River in position 43°3′54.4″ N, 086°14′14.8″ W (NAD 83).

(ii) *Enforcement date and time.* First weekend of August; 9 p.m. to 11 p.m.

(55) *Sturgeon Bay Yacht Club Evening on the Bay Fireworks; Sturgeon Bay, WI*—(i) *Location.* All waters of Sturgeon Bay, in the vicinity of the Sturgeon Bay Yacht Club, within the arc of a circle with a 500-foot radius from the fireworks launch site located on a barge in position 44°49′33″ N, 087°22′26″ W (NAD 83).

(ii) *Enforcement date and time.* The first Saturday of August; 9 p.m. to 11 p.m.

(56) *Hammond Marina Venetian Night Fireworks; Hammond, IN*—(i) *Location.* All waters of Hammond Marina and Lake Michigan within the arc of a circle with a 1000-foot radius from the fireworks launch site located in position 41°41′53″ N, 087°30′43″ W (NAD 83).

(ii) *Enforcement date and time.* The first Saturday of August; 9 p.m. to 11 p.m.

(57) *North Point Marina Venetian Festival Fireworks; Winthrop Harbor, IL*—(i) *Location.* All waters of Lake Michigan within the arc of a circle with a 1000-foot radius from the fireworks launch site located in position 42°28′55″ N, 087°47′56″ W (NAD 83).

(ii) *Enforcement date and time.* The second Saturday of August; 9 p.m. to 11 p.m.

(58) *Waterfront Festival Fireworks; Menominee, MI*— (i) *Location.* All waters of Green Bay, in the vicinity of Menominee Marina, within the arc of a circle with a 1000-foot radius from a fireworks barge in position 45°06′28.5″ N, 087°35′51.3″ W (NAD 83).

(ii) *Enforcement date and time.* Saturday following first Thursday in August; 9 p.m. to 11 p.m.

(59) *Ottawa Riverfest Fireworks; Ottawa, IL*—(i) *Location.* All waters of the Illinois River, at mile 239.7, within the arc of a circle with a 300-foot radius from the fireworks launch site located in position 41°20′29″ N, 088°51′20″ W (NAD 83).

(ii) *Enforcement date and time.* The first Sunday of August; 9 p.m. to 11 p.m.

(60) *Algoma Shanty Days Fireworks; Algoma, WI*—(i) *Location.* All waters of Lake Michigan and Algoma Harbor within the arc of a circle with a 1000-foot radius from the fireworks launch site located in position 44°36′24″ N, 087°25′54″ W (NAD 83).

(ii) *Enforcement date and time.* Sunday of the second complete weekend of August; 9 p.m. to 11 p.m.

(61) *New Buffalo Fireworks; New Buffalo, MI*—(i) *Location.* All waters of Lake Michigan and New Buffalo Harbor within the arc of a circle with a 1000-foot radius from the fireworks launch site located in position 41°48′09″ N, 086°44′49″ W (NAD 83).

(ii) *Enforcement date and time.* Will be enforced on either July 3rd or July 5th from 9 p.m. to 11 p.m.

(62) *Pentwater Homecoming Fireworks; Pentwater, MI*—(i) *Location.* All waters of Lake Michigan and the Pentwater Channel within the arc of a circle with a 1000-foot radius from the fireworks launch site located in position 43°46′56.5″ N, 086°26′38″ W (NAD 83).

(ii) *Enforcement date and time.* Saturday following the second Thursday of August; 9 p.m. to 11 p.m.

(63) *Chicago Air and Water Show; Chicago, IL*—(i) *Location.* All waters and adjacent shoreline of Lake Michigan and Chicago Harbor bounded by a line drawn from 41°55′54'' N at the shoreline, then east to 41°55′54″ N, 087°37′12″ W, then southeast to 41°54′00″ N, 087°36′00″ W (NAD 83), then southwestward to the northeast corner of the Jardine Water Filtration Plant, then due west to the shore.

(ii) *Enforcement date and time.* This event has historically occurred during the month of August. The Captain of the Port, Sector Lake Michigan, will establish enforcement dates that will be announced with a Notice of Enforcement and marine information broadcasts.

(64) *Downtown Milwaukee BID 21 Fireworks; Milwaukee, WI*—(i) *Location.* All waters of the Milwaukee River between the Kilbourn Avenue Bridge at 1.7 miles above the Milwaukee Pierhead Light to the State Street Bridge at 1.79 miles above the Milwaukee Pierhead Light.

(ii) *Enforcement date and time.* The third Thursday of November; 6 p.m. to 8 p.m.

(65) *New Years Eve Fireworks; Chicago, IL.*

(i) *Location.* All waters of Monroe Harbor and Lake Michigan within the arc of a circle with a 1,000-foot radius from the fireworks launch site located on a barge in position 41°52′41″ N, 087°36′37″ W (NAD 83).

(ii) *Enforcement date and time.* December 31; 11 p.m. to January 1; 1 a.m.

(66) *Cochrane Cup; Blue Island, IL*—(i) *Location.* All waters of the Calumet Saganashkee Channel from the South Halstead Street Bridge at 41°39′27″ N, 087°38′29″ W; to the Crawford Avenue Bridge at 41°39′05″ N, 087°43′08″ W; and the Little Calumet River from the Ashland Avenue Bridge at 41°39′7″ N, 087°39′38″ W; to the junction of the Calumet Saganashkee Channel at 41°39′23″ N, 087°39′00″ W (NAD 83).

(ii) *Enforcement date and time.* The first Saturday of May; 6:30 a.m. to 5 p.m.

(67) *World War II Beach Invasion Re-enactment; St. Joseph, MI*—(i) *Location.* All waters of Lake Michigan in the vicinity of Tiscornia Park in St. Joseph, MI beginning at 42°06′55″ N, 086°29′23″ W; then west/northwest along the north breakwater to 42°06′59″ N, 086°29′41″ W; the northwest 100 yards to 42°07′01″ N, 086°29′44″ W; then northeast 2,243 yards to 42°07′50″ N, 086°28′43″ W; the southeast to the shoreline at 42°07′39″ N, 086°28′27″ W; then southwest along the shoreline to the point of origin (NAD 83).

(ii) *Enforcement date and time.* The last Saturday of June; 8 a.m. to 2 p.m.

(68) *Ephraim Fireworks; Ephraim, WI*—(i) *Location.* All waters of Eagle Harbor and Lake Michigan within the arc of a circle with a 750-foot radius from the fireworks launch site located on a barge in position 45°09′18″ N, 087°10′51″ W (NAD 83).

(ii) *Enforcement date and time.* The third Saturday of June; 9 p.m. to 11 p.m.

(69) *Thunder on the Fox; Elgin, IL*—(i) *Location.* All waters of the Fox River, near Elgin, Illinois, between Owasco Avenue, located at approximate position 42°03′06″ N, 088°17′28″ W and the Kimball Street bridge, located at approximate position 42°02′31″ N, 088°17′22″ W (NAD 83).

(ii) *Enforcement date and time.* Friday, Saturday, and Sunday of the third weekend in June; 10 a.m. to 7 p.m. each day.

(70) *Olde Ellison Bay Days Fireworks Display, Ellison Bay, Wisconsin*—(i) *Location.* All waters of Lake Michigan, in the vicinity of Ellison Bay Wisconsin, within a 400 foot radius from the fireworks launch site located on a barge in position 45°15′36″ N, 087°05′03″ W (NAD 83).

(ii) *Enforcement date and time.* The fourth Saturday of June; 9 p.m. to 10 p.m.

(71) *Town of Porter Fireworks Display, Porter Indiana*—(i) *Location.* All waters of Lake Michigan within the arc of a circle with a 1,000 foot radius from the fireworks launch site located in position 41°39′56″ N, 087°03′57″ W (NAD 83).

(ii) *Enforcement date and time.* The first Saturday of July; 8:45 p.m. to 9:30 p.m.

(72) *City of Menasha 4th of July Fireworks, Lake Winnebago, Menasha, Wisconsin*—(i) *Location.* All U.S. navigable waters of Lake Michigan and the Fox River within the arc of a circle with an 800 foot radius from the fireworks launch site at position 41°39′56″ N, 087°03′57″ W (NAD 83).

(ii) *Enforcement date and time.* July 4; 9 p.m. to 10:30 p.m.

(73) *ISAF Nations Cup Grand Final Fireworks Display, Sheboygan, Wisconsin*—(i) *Location.* All waters of Lake Michigan and Sheboygan Harbor, in the vicinity of the south pier in Sheboygan Wisconsin, within a 500 foot radius from the fireworks launch site located on land in position 43°44′55″ N, 087°41′51″ W (NAD 83).

(ii) *Enforcement date and time.* September 13; 7:45 p.m. to 8:45 p.m.

(74) *Magnificent Mile Fireworks Display, Chicago, Illinois*—(i) *Location.* All waters and adjacent shoreline of the Chicago River bounded by the arc of the circle with a 210 foot radius from the fireworks launch site with its center in approximate position of 41°53′21″ N, 087°37′24″ W (NAD 83).

(ii) *Enforcement date and time.* The third weekend in November; sunset to termination of display.

(75) *Lubbers Cup Regatta; Spring Lake, MI*—(i) *Location.* All waters of Spring Lake in Spring Lake, Michigan within a rectangle that is approximately 6,300 by 300 feet. The rectangle will be bounded by the points beginning at 43°04′55″ N, 086°12′32″ W; then east to 43°04′57″ N, 086°11′6″ W; then south to 43°04′54″ N, 086°11′5″ W; then west to 43°04′52″ N, 086°12′32″ W; then north back to the point of origin [NAD 83].

(ii) *Enforcement date and time.* April 12 from 3:00 p.m. until 7:00 p.m., and April 13 from 8:00 a.m. until 3:00 p.m.

(76) *Chicago Match Cup Race; Chicago, IL*—(i) *Location.* All waters of Chicago Harbor in the vicinity of Navy Pier and the Chicago Harbor break wall bounded by coordinates beginning at 41°53′37″ N, 087°35′26″ W; then south to 41°53′24″ N, 087°35′26″ W; then west to 41°53′24″ N, 087°35′55″ W; then north to 41°53′37″ N, 087°35′55″ W; then back to point of origin [NAD 83].

(ii) *Enforcement date and time.* This event has historically occurred during the month of August. The Captain of the Port, Sector Lake Michigan, will establish enforcement dates that will be announced with a Notice of Enforcement and marine information broadcasts.

(77) *Chicago to Mackinac Race; Chicago, IL*—(i) *Location.* All waters of Lake Michigan in the vicinity of the Navy Pier at Chicago IL, within a rectangle that is approximately 1500 by 900 yards. The rectangle is bounded by the coordinates beginning at 41°53′15.1″ N, 087°35′25.8″ W; then south to 41°52′48.7″ N, 087°35′25.8″ W; then east to 41°52′49.0″ N, 087°34′26.0″ W; then north to 41°53′15″ N, 087°34′26″ W; then west, back to point of origin [NAD 83].

(ii) *Enforcement date and time.* This event has historically occurred in the month of July. The Captain of the Port, Sector Lake Michigan, will establish enforcement dates that will be announced with a Notice of Enforcement and marine information broadcasts.

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

(1) Designated representative means any Coast Guard commissioned, warrant, or petty officer designated by the Captain of the Port, Sector Lake Michigan, to monitor a safety zone, permit entry into a zone, give legally enforceable orders to persons or vessels within a safety zone, and take other actions authorized by the Captain of the Port, Sector Lake Michigan.

(2) Public vessel means a vessel that is owned, chartered, or operated by the United States, or by a State or political subdivision thereof.

(c) *Regulations.* (1) The general regulations in 33 CFR 165.23 apply.

(2) All persons and vessels must comply with the instructions of the Captain of the Port, Sector Lake Michigan, or his or her designated representative. Upon being hailed by the U.S. Coast Guard by siren, radio, flashing light or other means, the operator of a vessel shall proceed as directed.

(3) All vessels must obtain permission from the Captain of the Port, Sector Lake Michigan, or his or her designated representative to enter, move within or exit a safety zone established in this section when the safety zone is enforced. Vessels and persons granted permission to enter one of the safety zones listed in this section shall obey all lawful orders or directions of the Captain of the Port, Sector Lake Michigan, or his or her designated representative. While within a safety zone, all vessels shall operate at the minimum speed necessary to maintain a safe course.

(d) *Suspension of enforcement.* If the Captain of the Port, Sector Lake Michigan, suspends enforcement of any of these zones earlier than listed in this section, the Captain of the Port, Sector Lake Michigan, or his or her designated representative will notify the public by suspending the respective Broadcast Notice to Mariners.

(e) *Exemption.* Public vessels, as defined in paragraph (b) of this section, are exempt from the requirements in this section.

(f) *Waiver.* For any vessel, the Captain of the Port, Sector Lake Michigan, or his or her designated representative may waive any of the requirements of this section, upon finding that operational conditions or other circumstances are such that application of this section is unnecessary or impractical for the purposes of safety or environmental safety.

Dated: March 22, 2013.

M.W. Sibley,

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

[FR Doc. 2013–07911 Filed 4–4–13; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2012–0139; FRL–9381–7]

Flumioxazin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of flumioxazin in or on multiple commodities which are identified and discussed later in this document. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective April 5, 2013. Objections and requests for hearings must be received on or before June 4, 2013, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2012–0139, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Andrew Ertman, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 308–9367; email address: *ertman.andrew@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2012–0139 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 June 4, 2013. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2012–0139, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of May 2, 2012 (77 FR 25954) (FRL–9346–1), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2E7982) by IR–4, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR 180.568 be amended by establishing tolerances for residues of the herbicide flumioxazin, 2-[7-fluoro-3,4-dihydro-3-oxo-4-(2-propynyl)-2*H*-1,4-benzoxazin-6-yl]-4,5,6,7-tetrahydro-1*H*-isoindole-1,3(2*H*)-dione, in or on artichoke at 0.02 parts per million (ppm); cabbage and Chinese cabbage (tight-headed varieties only) at 0.02 ppm; olives, and olive oil at 0.02 ppm; pomegranate at 0.02 ppm; cactus fruit at 0.1 ppm, and cactus pads at 0.05 ppm. That document 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 modified the levels at which tolerances are being established for some commodities. The reason for these changes 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 FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), 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 flumioxazin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with flumioxazin 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 general, flumioxazin has mild or low acute toxicity. Also, the subchronic and chronic toxicity studies demonstrated that toxic effects associated with flumioxazin include anemia as well as effects on the liver and the cardiovascular system. Developmental effects were observed in developmental rat studies but not in developmental rabbit studies. Hematologic (hematopoietic) effects of anemia were noted in rats, consisting of alterations in hemoglobin parameters. Increased renal toxicity in male rats was also reported following chronic exposure. There is no evidence of neurotoxicity or immunotoxicity in the recently submitted guideline studies. Increased quantitative susceptibility was seen in the rat developmental toxicity studies. Fetal effects were observed in the absence of maternal toxicity. In addition, both increased qualitative and quantitative susceptibility were observed in the rat reproduction study. Severe fetal effects were observed at lower doses than milder parental effects. In most of the available mutagenicity studies, flumioxazin was negative for mutagenicity; however, aberrations were seen in a chromosomal aberration assay (CHO cells). Based on the lack of evidence of carcinogenicity in mice and rats, flumioxazin is classified as ''not likely to be carcinogenic to humans.''

Specific information on the studies received and the nature of the adverse effects caused by flumioxazin 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 docket ID number EPA–HQ–OPP–2012–0139 on pages 43–48 of the document titled ''Flumioxazin. Human Health Risk Assessment for the Proposed Uses on Artichoke, Cabbage, Olive, Pomegranate, and Prickly Pear Cactus''.

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 flumioxazin used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of September 21, 2012 (77 FR 58493) (FRL–9358–3).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to flumioxazin, EPA considered exposure under the petitioned-for tolerances as well as all existing flumioxazin tolerances in 40 CFR 180.568. EPA assessed dietary exposures from flumioxazin 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 flumioxazin. In estimating acute dietary exposure, EPA used food consumption information from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA) from 2003–2008. As to residue levels in food, EPA assumed tolerance level residues and 100 percent crop treated (PCT) for all proposed and registered commodities. In addition, EPA used default concentration factors to estimate residues of flumioxazin in processed commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA NHANES/WWEIA from 2003–2008. As to residue levels in food, EPA assumed tolerance level residues and 100 PCT for all proposed and registered commodities. In addition, EPA used default concentration factors to estimate residues of flumioxazin in processed commodities.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that flumioxazin 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 flumioxazin. Tolerance level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* In the environment flumioxazin photodegrades very rapidly in water and on soil. Concentrations of flumioxazin and its major degradates (482–HA, APF, and THPA) are expected to be found in water; however, flumioxazin and the metabolites 482–HA and APF have been identified as the residues of concern in drinking water.

To estimate concentrations of flumioxazin including its major degradates of concern (482–HA and APF) in ground water, the Agency used a screening level water exposure model in the dietary exposure analysis and risk assessment. This simulation model took into account data on the physical, chemical, and fate/transport characteristics of flumioxazin. Since this chemical is currently registered for direct applications to water, surface water estimates are based on the use of flumioxazin as an aquatic herbicide where a maximum 400 parts per billion (ppb) concentration is maintained. Hydrolysis is considered the major route of dissipation for flumioxazin in the environment and the levels of degradates (482–HA and APF) increase continuously with time.

Based on the Screening Concentration in Ground Water (SCI–GROW) model the estimated drinking water concentrations (EDWCs) for both acute and chronic exposures of 482–HA and APF are estimated to be 45.27 ppb and 2.66 ppb, respectively, in ground water. EDWCs of parent flumioxazin are estimated to be negligible in ground water for both acute and chronic exposures. For surface water, the EDWCs for flumioxazin are estimated to be 400 ppb for acute exposures and no 482–HA and APF is expected to be present. For chronic exposures, EDWCs of flumioxazin and its major degradates

(482–HA and APF) are estimated to be 9.4, 21.6, and 110.1 ppb, respectively, for surface water resulting in an EDWC of 142 ppb (total).

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 400 ppb was used to assess the contribution to drinking water of flumioxazin. For chronic dietary risk assessment, the water concentration of value 142 ppb (the total EDWC for flumioxazin, 482–HA and APF in surface water) was used to assess the contribution to drinking water of flumioxazin and its major degradates (482–HA and APF).

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.*

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).

Flumioxazin is currently registered for uses that could result in residential exposures, including aquatic areas, ornamental gardens, ornamental trees, turf, and golf courses. EPA assessed residential exposure with the assumption that homeowner handlers wear shorts, short-sleeved shirts, socks, and shoes, and that they complete all tasks associated with the use of a pesticide product including mixing/loading, if needed, as well as the application. Residential handler exposure scenarios for both dermal and inhalation are considered to be short-term only, due to the infrequent use patterns associated with homeowner products.

EPA uses the term ''postapplication'' to describe exposure to individuals that occur as a result of being in an environment that has been previously treated with a pesticide. Flumioxazin is registered for use in many areas that can be frequented by the general population including residential areas, golf courses, lakes, and ponds. As a result, individuals can be exposed by entering these areas if they have been previously treated. Therefore, short-term and intermediate dermal postapplication exposures and risks were assessed for adults and children. In addition, oral post-application exposures and risks were assessed for children to be protective of possible hand-to-mouth, object-to-mouth, and soil ingestion activities that may occur on treated turf areas. 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 flumioxazin to share a common mechanism of toxicity with any other substances, and flumioxazin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that flumioxazin 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.* Evidence of increased susceptibility to fetuses was observed in the oral and dermal developmental rat studies i.e. cardiovascular anomalies (ventricular septal defect) that occurred in the absence of maternal toxicity. Additionally, the rat reproduction study demonstrated evidence of qualitative and quantitative post-natal susceptibility because reproductive effects in offspring were observed at doses lower than those that caused parental/systemic toxicity, and because the reproductive effects in offspring were considered to be more severe than the parental/systemic effects.

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 for oral and dermal exposures, but be retained at 10X for inhalation exposures. That decision is based on the following findings:

i. The toxicity database for flumioxazin is largely complete with the exception of an inhalation developmental study, which was recently determined necessary, in order to better assess route-specific inhalation risks. In the absence of this study, a 10X FQPA safety factor to account for database uncertainty is needed to protect the safety of infants and children to assess risks for all inhalation exposure scenarios. The toxicity profile can be characterized for all effects, including potential developmental and reproductive toxicity, immunotoxicity and neurotoxicity with the current database.

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

iii. Although increased susceptibility was seen in the rat developmental and reproductive studies, EPA's concern for these effects is low, and there are no residual uncertainties for pre- and/or postnatal toxicity because:

a. The developmental toxicity NOAELs/LOAELs are well characterized after oral and dermal exposure;

b. The offspring toxicity NOAEL and LOAEL are well characterized in the reproduction study and

c. The points of departure for assessing risk to developing fetuses, infants, and children have been selected either from the developmental and reproductive toxicity studies from the chronic study which established a lower point of departure for chronic effects than the studies in pre- and postnatal animals. Thus, the regulatory endpoints for flumioxazin are protective of the increased susceptibility seen in the developmental and reproduction studies, and there are no residual concerns for these effects.

iv. There are no residual uncertainties identified in the exposure databases. The acute and chronic dietary analyses were based on tolerance-level residues and 100 PCT assumptions for all commodities. The dietary drinking water assessment utilized water concentration values generated by model and associated modeling parameters which are designed to provide conservative, health protective, high-end estimates of water

concentrations. The residential exposure assessment incorporates similarly conservative assumptions in the assessment of post-application exposure to children and in the incidental oral exposure assessment for children.

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.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to flumioxazin will occupy 75% of the aPAD for females 13–49 years old, the only population group of concern for acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to flumioxazin from food and water will utilize 44% of the cPAD for all infants less than 1 year old, the population subgroup receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of flumioxazin 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). Flumioxazin 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 flumioxazin.

Different methodologies were used for the presentation of short-term aggregate risk for adults and children. An aggregate risk estimate (ARI) approach was required to estimate short-term adult aggregate risk because there are different levels of concern (LOCs) for adult dermal and inhalation exposures, 100 and 1,000, respectively. For short-term child aggregate risk, the combined MOE approach was used because the endpoint of concern (decreased pup weight) and the LOC are the same. 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 ARI of 1.12 for adults and aggregate MOE of 182 for children. Because EPA's level of concern for flumioxazin is an ARI of 1 or below and a MOE of 100 or below, these aggregate risk estimates 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). Since the short- and intermediate-term toxicological endpoints for flumioxazin are the same for each route of exposure, only short-term exposures were assessed.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, flumioxazin 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 flumioxazin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography/nitrogen-phosphorus detection (GC/NPD) method, Valent Method RM30–A–1) 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; email 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 United Nations 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 MRLs for flumioxazin for any of the commodities covered by this document.

C. Revisions to Petitioned-For Tolerances

The Agency has revised the levels for prickly pear cactus fruit and pads from 0.1 and 0.05 to 0.07 and 0.06, respectively. The modifications were due to the Agency's use of the Organization for Economic Co-operation and Development (OECD) calculation procedures to determine the appropriate tolerance levels.

Additionally, the petition proposed a tolerance for olive oil at 0.02 ppm. The Agency reviewed an olive oil processing study and found that the residue levels found in olive oil were the same as those found in olives. As such, the Agency has determined that a tolerance for olive is appropriate, and a separate tolerance on olive oil is not necessary.

V. Conclusion

Therefore, tolerances are established for residues of flumioxazin, 2-[7-fluoro-3,4-dihydro-3-oxo-4-(2-propynyl)-2*H*-1,4-benzoxazin-6-yl]-4,5,6,7-tetrahydro-1*H*-isoindole-1,3(2*H*)-dione, in or on artichoke, globe at 0.02 ppm; cabbage at 0.02 ppm; cabbage, Chinese, napa at 0.02 ppm; olive at 0.02 ppm; pomegranate at 0.02 ppm; prickly pear, fruit at 0.07 ppm; and prickly pear, pads at 0.06 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this 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 FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This 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 FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this 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) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: March 28, 2013.

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 § 180.568, add alphabetically the following commodities to the table in paragraph (a) to read as follows:

§ 180.568 Flumioxazin; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Artichoke, globe	0.02
* * * * *	
Cabbage	0.02
Cabbage, Chinese, napa	0.02
* * * * *	
Olive	0.02
* * * * *	
Pomegranate	0.02
Prickly pear, fruit	0.07
Prickly pear, pads	0.06
* * * * *	

* * * * *

[FR Doc. 2013–07980 Filed 4–4–13; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 68

[Docket No. NIH–2008–0003]

RIN 0905–AA43

National Institutes of Health Loan Repayment Programs

AGENCY: National Institutes of Health, HHS.

ACTION: Final rule.

SUMMARY: As a part of the Department of Health and Human Services (HHS)'s ongoing retrospective review initiative, the National Institutes of Health (NIH) is rescinding the existing regulations for two of its eight loan repayment programs and issuing in their place a new consolidated set of regulations governing all of the NIH Loan Repayment Programs (LRPs). There are currently eight programs, including three for researchers employed by the NIH (Intramural LRPs) and five for non-NIH scientists (Extramural LRPs). The Intramural LRPs include the Loan Repayment Program for Research with Respect to Acquired Immune Deficiency Syndrome (or AIDS Research LRP); Loan Repayment Program for General Research (or General Research LRP), which includes a program for the Accreditation Council for Graduate Medical Education (ACGME) Fellows; and Loan Repayment Program for Clinical Researchers from Disadvantaged Backgrounds (or Clinical Research LRP for Individuals from Disadvantaged Backgrounds). The Extramural LRPs include the Loan Repayment Program for Contraception and Infertility Research (or Contraception and Infertility Research LRP); Loan Repayment Program for Clinical Researchers from Disadvantaged Backgrounds (or Clinical Research LRP for Individuals from Disadvantaged Backgrounds); Loan Repayment Program for Clinical Research (or Clinical Research LRP); Loan Repayment Program for Pediatric Research (or Pediatric Research LRP); and Loan Repayment Program for Health Disparities Research (or Health Disparities Research LRP).

DATES: This final rule is effective May 6, 2013.

FOR FURTHER INFORMATION CONTACT: Jerry Moore, NIH Regulations Officer, Office of Management Assessment, NIH, 6011 Executive Boulevard, Room 601, MSC 7669, Rockville, MD 20892; by email at *MooreJ@mail.nih.gov*; by fax on 301–402–0169 (not a toll-free number); or by telephone 301–496–4607 (not a toll-free number) for information about the rulemaking process. For program information, contact: NIH Division of Loan Repayment by email *lrp@nih.gov* or telephone 866–849–4047. For information regarding the requirements, the application deadline dates, and an online application for the NIH Loan Repayment Programs, refer to the NIH Loan Repayment Program Web site, *www.lrp.nih.gov*.

SUPPLEMENTARY INFORMATION: On November 4, 1988, Congress enacted the Health Omnibus Programs Extension of 1988, (Pub. L. 100–607). Title VI of this law amended the Public Health Service (PHS) Act by adding section 487A (42

U.S.C. 288–1) entitled Loan Repayment Program for Research with Respect to Acquired Immune Deficiency Syndrome. Subsequently, in the NIH Revitalization Act of 1993 (Pub. L. 103–43), Congress enacted the Loan Repayment Program for Research with Respect to Contraception and Infertility (section 487B; 42 U.S.C. 288–2); the Loan Repayment Program for Research Generally (section 487C; 42 U.S.C. 288–3); and the Loan Repayment Program for Clinical Researchers from Disadvantaged Backgrounds (section 487E; 42 U.S.C. 288–5). The Children's Health Act of 2000 (Pub. L. 106–310), which was enacted on October 17, 2000, added the Pediatric Research Loan Repayment Program (section 487F; [1] 42 U.S.C. 288–6). On November 13, 2000, the Clinical Research Enhancement Act, contained in the Public Health Improvement Act of 2000 (Pub. L. 106–505), enacted the Loan Repayment Program for Clinical Research (section 487F; [2] 42 U.S.C. 288–5a). On November 22, 2000, the Minority Health and Health Disparities Research and Education Act of 2000 (Pub. L. 106–525) enacted the Loan Repayment Program for Health Disparities Research (section 485G, re-designated 464z–5 by Pub. L. 111–148; [3] 42 U.S.C. 285t–2).

Sections 487A, 487B, 487C, 487E, and 487F of the PHS Act authorize the Secretary of Health and Human Services to enter into contracts with qualified health professionals under which such professionals agree to conduct research in consideration of the Federal Government agreeing to repay, for each year of such service, not more than $35,000 of the principal and interest of the qualified educational loans of such professionals. Section 464z–5 authorizes the Director, National Institute on Minority Health and Health Disparities (NIMHD) to do the same.

In return for these loan repayments, applicants must agree to participate in qualifying research for an initial period of not less than two years (or a minimum of three years for the General Research LRP) as one of the following:

(a) An NIH employee (for Intramural LRPs), or

(b) A health professional engaged in qualifying research supported by a domestic nonprofit foundation, nonprofit professional association, or other nonprofit institution (e.g., university), or a U.S. or other government agency (Federal, state or local).

The purpose of the LRP programs is to recruit and retain highly qualified health professionals as biomedical and behavioral researchers. LRP programs offer educational loan repayment for participants who agree, by written contract, to engage in qualifying domestic nonprofit-supported research at a qualifying non-NIH institution, or as an NIH employee, for a minimum of two years (or three years for the Intramural General Research LRP).

Currently, the Clinical Research LRP for Individuals from Disadvantaged Backgrounds and the Contraception and Infertility Research LRP are governed by their own individual regulations while the other LRPs are without regulations. We are consolidating the regulations into a single set of regulations governing all the LRPs. More specifically, we are rescinding the current regulations codified at 42 CFR Part 68a, entitled ''National Institutes of Health Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds (CR–LRP),'' and 42 CFR Part 68c, entitled ''National Institute of Child Health and Human Development Contraception and Infertility Research Loan Repayment Program,'' and issuing a new consolidated set of regulations at 42 CFR Part 68, entitled ''National Institutes of Health Loan Repayment Programs (LRPs),'' to govern each of the eight individual NIH Loan Repayment Programs, the three that are for researchers employed by the NIH (Intramural LRPs) and the five that are for non-NIH scientists (Extramural LRPs). The three Intramural LRPs include the AIDS Research LRP, General Research LRP, and Clinical Research LRP for Individuals from Disadvantaged Backgrounds. The five Extramural LRPs include the Contraception and Infertility Research LRP, Clinical Research LRP for Individuals from Disadvantaged Backgrounds, Clinical Research LRP, Pediatric Research LRP, and Health Disparities Research LRP.

We announced our intentions to take these rulemaking actions in the notice of proposed rulemaking (NPRM) ''National Institutes of Health Loan Repayment Programs,'' that we published in the **Federal Register** on February 22, 2012 (77 FR 10455–10461). In the NPRM we provided a 60-day public comment period. The public comment period expired April 23, 2012. We received only one public comment. Because the comment did not address the regulations per se, but simply questioned the need for any loan repayment, we did not view the comment as relevant to this rulemaking action. Consequently, the final NIH LRP regulations that are set forth in this final rule are essentially identical to the proposed regulations that we set forth in the NPRM. We provide the following as public information.

Regulatory Impact Analysis

We have examined the impacts of this rule as required by E.O. 12866, ''Regulatory Planning and Review'' (September 30, 1993), E.O. 13563, ''Improving Regulation and Regulatory Review'' (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and E.O. 13132, ''Federalism'' (August 4, 1999).

Executive Order 12866

E.O. 12866, as supplemented by Executive Order 13563, 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 and other advantages, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any one year). Based on our analysis, we believe the rulemaking does not constitute an economically significant regulatory action.

The Regulatory Flexibility Act

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of the rule on small entities. For the purpose of this analysis, small entities include small business concerns as defined by the Small Business Administration (SBA), usually businesses with fewer than 500 employees. Applicants who are eligible to apply for the loan repayment awards are individuals, not small entities. The Secretary certifies that this rule will not have a significant impact on a significant number of small entities.

[1] So in law. There are two sections 487F. Section 1002(b) of Public Law 106–310 (114 Stat. 1129), inserted section 487F above. Subsequently, section 205 of Public Law 106–505 (114 Stat. 2329), which relates to the Loan Repayment Program for Clinical Researchers, inserted a section 487F after section 487E.

[2] 205 of Public Law 106–505 (114 Stat. 2329), inserted section 487F after section 487E. Previously, section 1002(b) of Public Law 106–310 (114 Stat. 1129), which relates to the Pediatric Research Loan Repayment Program, inserted section 487F after section 487E.

[3] Section 485G of the PHS Act, enacted by Public Law 106–525, was redesignated section 464z-5 by Public Law 111–148.

Section 202(a) of the Unfunded Mandates Reform Act of 1995

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement that includes an assessment of anticipated costs and benefits before proposing ''any rule that includes any Federal mandate that may result in the expenditure by state, local, and tribal organizations, in the aggregate, or by the private sector, of ''$100,000,000 or more (adjusted annually for inflation with base year of 1995) in any one year.'' The current inflation-adjusted threshold for 2012 is approximately $145.5 million. The Secretary certifies that this rule does not mandate any spending by State, local or tribal government in the aggregate or by the private sector. Participation in the NIH loan repayment programs is voluntary and not mandated.

Executive Order 13132

E.O. 13132, Federalism, requires that Federal agencies consult with state and local government officials in the development of regulatory policies with federalism implications. We reviewed the rule as required under the Order, and determined that it does not have ''federalism implications'' because it will not have substantial direct effect on the states, 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.

Paperwork Reduction Act

This proposed rule does not contain any new information collection requirements that are subject to Office of Management and Budget (OMB) approval under the Paperwork Reduction Act of 1995 (44 U.S.C. 35). More specifically, § 68.6 of this rule is a reporting requirement, but the specifics of the burden are determined in the approved application forms used by the NIH Loan Repayment Programs and have been approved under OMB No. 0925–0361, Expiration Date: June 30, 2014. Additionally, §§ 68.3(c), 68.3(e), 68.11(c), 68.14(c), 68.14(d), and 68.16(a) of this rule are reporting requirements and/or recordkeeping requirements, but they are also covered under OMB No. 0925–0361.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbered programs affected by the proposed regulations are:

93.209—Contraception and Infertility Research Loan Repayment Program
93.220—Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds
93.232—Loan Repayment Program for General Research
93.280—NIH Loan Repayment Program for Clinical Researchers
93.285—NIH Pediatric Research Loan Repayment Program
93.307—Minority Health and Health Disparities Research
93.308—Extramural Loan Repayment for Individuals from Disadvantaged Backgrounds Conducting Clinical Research
93.936—NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program

List of Subjects

42 CFR Parts 68, 68a, and 68c

Health professions, Loan repayment programs—health, Medical research.

For reasons presented in the preamble, and under the authority of 5 U.S.C 301 and 42 U.S.C. 216, HHS amends Title 42 of the Code of Federal Regulations by removing parts 68a and 68c and adding part 68 to read as follows:

PART 68—NATIONAL INSTITUTES OF HEALTH (NIH) LOAN REPAYMENT PROGRAMS (LRPs)

Sec.
68.1 What is the scope and purpose of the NIH LRPs?
68.2 Definitions.
68.3 Who is eligible to apply?
68.4 Who is eligible to participate?
68.5 Who is ineligible to participate?
68.6 How do individuals apply to participate in the NIH LRPs?
68.7 How are applicants selected to participate in the NIH LRPs?
68.8 What do the NIH LRPs provide to participants?
68.9 What loans qualify for repayment?
68.10 What loans are ineligible for repayment?
68.11 What does an individual have to do in return for loan repayments received under the NIH LRPs?
68.12 How does an individual receive loan repayments beyond the initial applicable contract period?
68.13 What will happen if an individual does not comply with the terms and conditions of participation in the NIH LRPs?
68.14 Under what circumstances can the service or payment obligation be canceled, waived, or suspended?
68.15 When can an NIH LRP payment obligation be discharged in bankruptcy?
68.16 Additional conditions.
68.17 What other regulations and statutes apply?

Authority: 42 U.S.C. 254o, 42 U.S.C. 288–1, 42 U.S.C. 288–2, 42 U.S.C. 288–3, 42 U.S.C. 288–5, 42 U.S.C. 288–5a, 42 U.S.C. 288–6, 42 U.S.C. 285t–2.

§ 68.1 What are the scope and purpose of the NIH LRPs?

The regulations of this part apply to the award of educational loan payments authorized by sections 487A, 487B, 487C, 487E, 487F,[1] and 464z–5 of the Public Health Service Act (42 U.S.C. 288–1, 42 U.S.C. 288–2, 42 U.S.C. 288–3, 42 U.S.C. 288–5, 42 U.S.C. 288–5a, 42 U.S.C. 288–6, 42 U.S.C. 285t–2). The purpose of these programs is to address the need for biomedical and behavioral researchers by providing an economic incentive to appropriately qualified health professionals who are engaged in qualifying research supported by domestic nonprofit funding or as employees of the NIH. The NIH Loan Repayment Programs include eight separate programs, three that are Intramural (for NIH researchers) and five that are Extramural (for non-NIH researchers).

(a) The Intramural LRPs include:

(1) Loan Repayment Program for Research with Respect to Acquired Immune Deficiency Syndrome (or AIDS Research LRP);

(2) Loan Repayment Program for General Research (or General Research LRP), including a program for Accreditation Council for Graduate Medical Education (ACGME) Fellows; and

(3) Loan Repayment Program for Clinical Researchers from Disadvantaged Backgrounds (or Clinical Research LRP for Individuals from Disadvantaged Backgrounds). This program is also included as a separate program under the Extramural LRPs.

(b) The Extramural LRPs include:

(1) Loan Repayment Program for Contraception and Infertility Research (or Contraception and Infertility Research LRP);

(2) Loan Repayment Program for Clinical Researchers from Disadvantaged Backgrounds (or Clinical Research LRP for Individuals from Disadvantaged Backgrounds);

(3) Loan Repayment Program for Clinical Researchers (or Clinical Research LRP);

(4) Loan Repayment Program for Pediatric Research (or Pediatric Research LRP); and

(5) Loan Repayment Program for Health Disparities Research (or Health Disparities Research LRP).

[1] There are two sections 487F. Section 1002(b) of Public Law 106–310 added section 487F, 42 U.S.C. 288–6, the Pediatric Research Loan Repayment Program. Subsequently, section 205 of Public Law 106–505 also added section 487F, 42 U.S.C. 288–5a, enacting the Loan Repayment Program for Clinical Researchers.

§ 68.2 Definitions.

As used in this part:

Act means the Public Health Service Act, as amended (42 U.S.C. 201 et seq.).

AIDS Research means research activities related to the Acquired Immunodeficiency Syndrome that qualify for inclusion in the AIDS Research LRP.

Applicant means an individual who applies to and meets the eligibility criteria for the NIH LRPs.

Breach of contract results when a participant fails to complete the research service or other obligation(s) required under the contract and may be subject to assessment of monetary damages and penalties as defined by statute.

Clinical research is patient-oriented clinical research conducted with human subjects, or research on the causes and consequences of disease in human populations involving material of human origin (such as tissue specimens and cognitive phenomena) for which an investigator or colleague directly interacts with human subjects in an outpatient or inpatient setting to clarify a problem in human physiology, pathophysiology or disease, or epidemiologic or behavioral studies, outcomes research or health services research, or developing new technologies, therapeutic interventions, or clinical trials.

Commercial loans means loans made for educational purposes by banks, credit unions, savings and loan associations, not-for-profit organizations, insurance companies, schools, and other financial or credit institutions that are subject to examination and supervision in their capacity as lending institutions by an agency of the United States or of the state in which the lender has its principal place of business.

Contraception research is defined as research with the ultimate goal of providing new or improved methods of preventing pregnancy.

Current payment status means that a qualified educational loan is not past due in its payment schedule, as determined by the lending institution.

Debt threshold means the minimum amount of qualified educational debt an individual must have, on their program eligibility date, in order to be eligible for LRP benefits, as established by the Secretary.

Director means the Director of the National Institute on Minority Health and Health Disparities (NIMHD) or designee.

Educational expenses means the cost of the health professional's undergraduate, graduate, and health professional school's education, including the tuition expenses and other educational expenses such as living expenses, fees, books, supplies, educational equipment and materials, and laboratory expenses.

Extramural LRPs refers to those programs for which health professionals, who are not NIH employees and have program-specified degrees and domestic nonprofit support, are eligible to apply. The Extramural LRPs include:

(1) Contraception and Infertility Research LRP;

(2) Clinical Research LRP for Individuals from Disadvantaged Backgrounds;

(3) Clinical Research LRP;

(4) Pediatric Research LRP; and

(5) Health Disparities Research LRP.

General research pertains to research that falls within the basic science or clinical research parameters and is not targeted toward a specific area (e.g., AIDS) or type of research (e.g., clinical research). The focus is on biomedical and behavioral research studies and investigations across a variety of scientific disciplines within the mission of the NIH.

Government loans means educational loans made by U.S. Federal, state, county, or city agencies that are authorized by law to make such loans.

Health disparities population: a population is a health disparity population if, as determined by the Director after consultation with the Director of the Agency for Healthcare Research and Quality, there is a significant disparity in the overall rate of disease incidence, prevalence, morbidity, mortality, or survival rates in the population as compared to the health status of the general population.

Individual from disadvantaged background. (1) Comes from an environment that inhibited the individual from obtaining the knowledge, skill and ability required to enroll in and graduate from a health professions school; or

(2) Comes from a family with an annual income below a level based on low-income thresholds according to family size published by the U.S. Bureau of the Census, adjusted annually for changes in the Consumer Price Index, and adjusted by the Secretary for use in HHS programs. The Secretary periodically publishes these income levels in the **Federal Register**.

Infertility research is defined as research with the long-range objective of evaluating, treating, or ameliorating conditions that result in the failure of couples to either conceive or bear young.

Institute or Center (IC) means an Institute or Center of the National Institutes of Health (NIH).

Intramural LRPs refers to those programs for which applicants must be employed by the NIH. The intramural LRPs include:

(1) AIDS Research LRP;

(2) General Research LRP; and

(3) Clinical Research LRP for Individuals from Disadvantaged Backgrounds.

Institutional base salary or salary is the annual income or compensation that the organization pays for the applicant's appointment, whether the time is spent on research, teaching, patient care, or other activities.

Living expenses means the reasonable cost of room and board, transportation and commuting costs, and other reasonable costs incurred during an individual's attendance at an educational institution and is part of the educational loan.

Loan Repayment Programs (LRPs) refers to the NIH Loan Repayment Programs, including those authorized by sections 487A, 487B, 487C, 487E, 487F, and 464z-5 of the Act, as amended.

Loan Repayment Program contract refers to the agreement signed by an applicant and the Secretary or Director (for the following extramural LRPs: Health Disparities Research LRP and Clinical Research LRP for Individuals from Disadvantaged Backgrounds only). Under such an agreement, an Intramural LRP applicant agrees to conduct qualified research as an NIH employee, and an Extramural LRP applicant agrees to conduct qualified research supported by domestic nonprofit funding, in exchange for repayment of the applicant's qualified educational loan(s) for a prescribed period.

NIH refers to the National Institutes of Health.

Nonprofit funding/support: applicants must conduct qualifying research supported by a domestic nonprofit foundation, nonprofit professional association, or other nonprofit institution (e.g., university), or a U.S. or other government agency (Federal, state or local). A domestic foundation, professional association, or institution is considered to be nonprofit if exempt from Federal tax under the provisions of Section 501 of the Internal Revenue Code (26 U.S.C. 501).

Participant means an individual whose application to any of the NIH LRPs has been approved and whose Program contract has been executed by the Secretary or the Director.

Pediatric research is defined as research directly related to diseases, disorders, and other conditions in

children, including pediatric pharmacology.

Program refers to the NIH Loan Repayment Program, or LRP.

Program eligibility date means the date on which an individual's LRP contract is executed by the Secretary or the Director.

Qualified Educational Loans and Interest/Debt (see *Educational Expenses*) as established by the Secretary, include Government and commercial educational loans and interest for:

(1) Undergraduate, graduate, and health professional school tuition expenses;

(2) Other reasonable educational expenses required by the school(s) attended, including fees, books, supplies, educational equipment and materials, and laboratory expenses; and

(3) Reasonable living expenses, including the cost of room and board, transportation and commuting costs, and other reasonable living expenses incurred.

Reasonable educational and living expenses means those educational and living expenses that are equal to or less than the sum of the school's estimated standard student budget for educational and living expenses for the degree program and for the year(s) during which the participant was enrolled in school. If there is no standard budget available from the school, or if the participant requests repayment for educational and living expenses that exceed the standard student budget, reasonableness of educational and living expenses incurred must be substantiated by additional contemporaneous documentation, as determined by the Secretary.

Repayable debt means the proportion, as established by the Secretary, of an individual's total qualified educational debt that can be paid by an NIH LRP.

Salary has the same meaning as *institutional base salary.*

School means undergraduate, graduate, and health professions schools that are accredited by a body or bodies recognized for accreditation purposes by the U.S. Secretary of Education.

Secretary means the Secretary of Health and Human Services or designee.

Service means the Public Health Service.

State means one of the fifty states, the District of Columbia, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the U.S. Virgin Islands, Guam, American Samoa, and the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau.

Waiver means a waiver of the service obligation granted by the Secretary when compliance by the participant is impossible or would involve extreme hardship, or where enforcement with respect to the individual would be unconscionable. (See *Breach of contract.*)

Withdrawal means a request by a participant, prior to the Program making payments on his or her behalf, for withdrawal from Program participation. A withdrawal is without penalty to the participant and without obligation to the Program.

§ 68.3 Who is eligible to apply?

To be eligible for consideration for the NIH LRPs, applicants must meet the following criteria:

(a) Be citizens, nationals, or permanent residents of the United States;

(b) Have the necessary degree from an accredited institution as determined by the NIH to be consistent with the needs of the LRP;

(c)(1) For Intramural LRPs only: Applicants must be employed by the NIH and engage in qualified full-time research as specified by the LRP and be recommended by the employing IC or have a firm commitment of employment from an authorized official of the NIH;

(2) For Extramural LRPs only: Applicants must be conducting qualified research for an average of at least 20 hours per week that is supported by a domestic nonprofit foundation, nonprofit professional association, or other nonprofit institution (e.g., university), or a U.S. or other government agency (Federal, state or local);

(d) Have total qualifying educational loan debt as determined on the program eligibility date;

(e) The NIH or the employing institution must provide an assurance that the applicant will be employed/appointed and provided research support for the applicable term of the LRP contract; and

(f) Recipients of LRP awards must conduct their research in accordance with applicable Federal, state, and local law (e.g., applicable human subject protection regulations).

(g) For Clinical Research for Individuals from Disadvantaged Background only: Individual must be from a disadvantaged background. (See § 68.2, Definitions, *Individual from disadvantaged background.*)

§ 68.4 Who is eligible to participate?

To be eligible to participate in the NIH LRPs, individuals must:

(a) Meet the eligibility requirements specified in § 68.3 of this part;

(b) Not be ineligible for participation as specified in § 68.5 of this part;

(c) Engage in qualified research for the contractual period;

(d) Engage in such research for the percentage of time specified for the particular LRP; and

(e) Comply with all other terms and conditions of the applicable Loan Repayment Program.

§ 68.5 Who is ineligible to participate?

The following individuals are ineligible for NIH LRP participation:

(a) Persons who do not meet the eligibility requirements as specified under § 68.3 of this part;

(b) Any individual who has or had a Federal judgment lien against his/her property arising from Federal debt;

(c) Persons who owe an obligation of health professional service to the Federal Government, a state, or other entity, unless deferrals or extensions are granted for the length of the service of their LRP contract. The following are examples of programs that have a service obligation:

(1) Armed Forces (Army, Navy, or Air Force) Professions Scholarship Program,

(2) Exceptional Financial Need (EFN) Scholarship Program,

(3) Financial Assistance for Disadvantaged Health Professions Students (FADHPS),

(4) Indian Health Service (IHS) Scholarship Program,

(5) National Health Service Corps (NHSC) Scholarship Program,

(6) National Research Service Award (NRSA) Program, and/or Loan Repayment Programs, NURSE Corps Scholarship and Loan Repayment Programs,

(7) NIH Undergraduate Scholarship Program (UGSP),

(8) Physicians Shortage Area Scholarship Program,

(9) Primary Care Loan (PCL) Program, and

(10) Public Health Service Scholarship (PHS) Program;

(d) For extramural LRPs only: Individuals who receive any research funding support or salary from a for-profit institution or organization, or Federal Government employees working more than 20 hours per week;

(e) Current recipients of NIH intramural training awards, e.g., NIH Intramural Research Training Awards (IRTA) or Cancer Research Training Awards (CRTA);

(f) Individuals conducting research for which funding is precluded by Federal law, regulation, or HHS/NIH policy or that does not comply with applicable Federal, state, and local law regarding the conduct of the research (e.g.,

applicable human subject protection regulations);

(g) Individuals with only ineligible loans or loans that are not educational; and

(h) Individuals who do not have sufficient qualifying educational debt to meet the debt threshold.

§ 68.6 How do individuals apply to participate in the NIH LRPs?

An application for participation in an NIH LRP shall be submitted to the NIH, which is responsible for the Program's administration, in such form and manner as the Secretary prescribes.

§ 68.7 How are applicants selected to participate in the NIH LRPs?

The NIH LRP awards are competitive. To be selected for participation in an NIH LRP, applicants must satisfy the following requirements:

(a) Applicants must meet the eligibility requirements specified in §§ 68.3 and 68.4 of this part.

(b) Applicants must not be ineligible for participation as specified in § 68.5 of this part.

(c) Upon receipt, applications for any of the NIH LRPs will be reviewed for eligibility and completeness by the NIH Division of Loan Repayment. Incomplete or ineligible applications will not be processed or reviewed further.

(d)(1) Applications for the Intramural LRPs that are deemed eligible and complete are submitted to the Loan Repayment Committee (LRC), which reviews, ranks, and approves/disapproves LRP awards. The LRC is composed of senior intramural scientists, including basic (bench) and clinical researchers and science policy administrators. Since LRP participation in the Intramural programs is contingent upon NIH employment, applicants must be recommended by the employing IC of the NIH to be considered by the LRC.

(2) Applications for the Extramural LRPs that are deemed eligible and complete will be referred by the NIH Center for Scientific Review (CSR) to an appropriate NIH IC for peer review. In evaluating the application, reviewers are directed to consider the following components and how they relate to the likelihood that the applicant will continue in a research career:

(i) Applicant's potential to pursue a career in research as defined by the appropriate LRP:

(A) Appropriateness of the applicant's previous training and experience to prepare for a research career.

(B) Appropriateness of the proposed research activities during the LRP contract to foster a career in research.

(C) Commitment to a research career, as reflected by the personal statement of long-term career goals and plan to achieve those goals.

(D) Strength of the letters of recommendations attesting to the applicant's potential for a successful career in research.

(ii) Quality of the overall environment to prepare the applicant for a research career:

(A) Quality and availability of appropriate scientific mentors and colleagues to help achieve or enhance the applicant's research independence, including the mentors' record in mentoring researchers, funding history, and research productivity.

(B) Quality and appropriateness of institutional resources and facilities.

(iii) For the Health Disparities Research LRP, at least 50 percent of the contracts are required by statute to be for appropriately qualified health professionals who are members of a health disparity population.

§ 68.8 What do the NIH LRPs provide to participants?

(a) Loan repayments: For each year of the applicable service period the individual agrees to serve, the NIH may pay up to $35,000 per year of a participant's repayable debt.

(b) Payments are made directly to a participant's lender(s). If there is more than one outstanding qualified educational loan, the NIH will repay the loans in the following order, unless the NIH determines significant savings would result from paying loans in a different order of priority:

(1) Loans guaranteed by the U.S. Department of Health and Human Services;

(2) Loans guaranteed by the U.S. Department of Education;

(3) Loans made or guaranteed by a state;

(4) Loans made by a school; and

(5) Loans made by other entities.

(c) Tax liability payments: In addition to the loan repayments, the NIH shall make tax payments in an amount equal to 39 percent of the total annual loan repayment to the Internal Revenue Service on the participant's behalf. The NIH may make additional payments to those participants who show increased Federal, State, and/or local taxes as a result of loan repayments.

(d) Under paragraphs (a), (b), and (c) of this section, the NIH will make loan and tax liability payments to the extent appropriated funds are available for these purposes.

§ 68.9 What loans qualify for repayment?

The NIH LRPs will repay participants' lenders the principal, interest, and related expenses of qualified U.S. Government and commercial educational loans obtained by participants for the following:

(a) Undergraduate, graduate, and health professional school tuition expenses;

(b) Other reasonable educational expenses required by the school(s) attended, including fees, books, supplies, educational equipment and materials, and laboratory expenses; and

(c) Reasonable living expenses, including the cost of room and board, transportation and commuting costs, and other living expenses, as determined by the NIH.

§ 68.10 What loans are ineligible for repayment?

The following loans are ineligible for repayment under the NIH LRPs:

(a) Loans not obtained from a bank, credit union, savings and loan association, not-for-profit organization, insurance company, school, and other financial or credit institution that is subject to examination and supervision in its capacity as a lending institution by an agency of the United States or of the state in which the lender has its principal place of business;

(b) Loans for which supporting documentation is not available;

(c) Loans that have been consolidated with loans of other individuals, such as spouses or children;

(d) Loans or portions of loans obtained for educational or living expenses that exceed the standard of reasonableness as determined by the participant's standard school budget for the year in which the loan was made and are not determined by the NIH to be reasonable based on additional documentation provided by the individual;

(e) Loans, financial debts, or service obligations incurred under the following programs, or similar programs, which provide loans, scholarships, loan repayments, or other awards in exchange for a future service obligation:

(1) Armed Forces (Army, Navy, or Air Force) Professions Scholarship Program,

(2) Exceptional Financial Need (EFN) Scholarship Program,

(3) Financial Assistance for Disadvantaged Health Professions Students (FADHPS),

(4) Indian Health Service Scholarship Program,

(5) National Health Service Corps Scholarship Program,

(6) National Institutes of Health Undergraduate Scholarship Program (UGSP),

(7) National Research Service Award (NRSA) Program,

(8) Physicians Shortage Area Scholarship Program,

(9) Primary Care Loans (PCL), and

(10) Public Health Service Scholarship Program;

(f) Any loan in default, delinquent, or not in a current payment status;

(g) Any Federal educational loan debt—including debt arising from the conversion of a service obligation to a loan—that has been in default or written off as uncollectible is ineligible for repayment under the Program, even if currently considered to be in good standing;

(h) Loan amounts that participants were due to have been paid prior to the LRP contract start date;

(i) Parents PLUS loans (except the Graduate PLUS loans for students);

(j) Loans for which promissory notes have been signed after the LRP contract start date (with the exception of qualifying student loan consolidations); and

(k) Home equity loans or other noneducational loans.

§ 68.11 What does an individual have to do in return for loan repayments received under the NIH LRPs?

Individuals must agree to:

(a) Engage in qualified research for the applicable contract service period;

(b)(1) For Intramural LRPs: Engage in such research full-time as employees of NIH, or;

(2) For Extramural LRPs: Engage in such research for an average of 20 hours per week supported by a domestic nonprofit foundation, nonprofit professional association, or other nonprofit institution (e.g., university), or a U.S. or other government agency (Federal, state or local);

(c) Keep all loan accounts in good standing, provide timely documentation as needed, including payment verification, service verification, change of research, change of institution, etc. Failure to provide such documentation may result in early termination, and the individual may be subject to statutory financial penalties; and

(d) Satisfy all of the other terms and conditions of the LRP and the LRP Contract (e.g., Obligations of the Participant). Failure to adhere to the terms and conditions of the LRP contract may result in early termination, and the individual may be subject to statutory financial penalties.

§ 68.12 How does an individual receive loan repayments beyond the initial applicable contract period?

An individual may apply for a competitive extension contract for at least a one-year period if the individual is engaged in qualifying research and satisfies the eligibility requirements specified under §§ 68.3 and 68.4 of this part for the extension period and has remaining repayable debt as established by the Secretary.

§ 68.13 What will happen if an individual does not comply with the terms and conditions of participation in the NIH LRPs?

Program participants who breach their Loan Repayment Program Contracts will be subject to the applicable monetary payment provisions set forth at section 338E of the Act (42 U.S.C. 254o). Payment of any amount owed under section 338E of the Act shall be made within one year of the date the participant breached his or her Loan Repayment Program Contract, unless the NIH specifically authorizes a longer period. Terminations will not be considered a breach of contract in cases where such terminations are beyond the control of the participant as follows:

(a) Terminations for convenience of the government will not be considered a breach of contract and monetary damages will not be assessed.

(b) Occasionally, a participant's research assignment or funding may evolve and change to the extent that the individual is no longer engaged in approved research. Similarly, the research needs and priorities of the IC and/or the NIH may change to the extent that a determination is made that a health professional's skills may be better utilized in a nonresearch assignment. Normally, job changes of this nature will not be considered a breach of contract on the part of either the NIH or the participant. Under these circumstances, the following will apply:

(1) Program participation will cease as of the date an individual is no longer engaged in approved research;

(2) Based on the approval of the NIH, the participant will be released from the remainder of his or her service obligation without assessment of damages or monetary penalties. The participant in this case will be permitted to retain all Program benefits made or owed by the NIH on his/her behalf up to the date the individual is no longer engaged in research, less the pro rata portion of any benefits advanced beyond the period of completed service.

§ 68.14 Under what circumstances can the service or payment obligation be canceled, waived, or suspended?

(a) Any obligation of a participant for service or payment will be canceled upon the death of the participant.

(b)(1) The NIH may waive or suspend any service or payment obligation incurred by the participant upon request whenever compliance by the participant:

(i) Is impossible;

(ii) Would involve extreme hardship to the participant; or

(iii) If enforcement of the service or payment obligation would be unconscionable.

(2) The NIH may approve a request for a suspension of the service or payment obligations for a period of up to one (1) year.

(c) Compliance by a participant with a service or payment obligation will be considered impossible if the NIH determines, on the basis of information and documentation as may be required, that the participant suffers from a permanent physical or mental disability resulting in the inability of the participant to perform the service or other activities that would be necessary to comply with the obligation.

(d) In determining whether to waive or suspend any or all of the service or payment obligations of a participant as imposing an undue hardship and being against good conscience, the NIH, on the basis of such information and documentation as may be required, will consider:

(1) The participant's present financial resources and obligations;

(2) The participant's estimated future financial resources and obligations; and

(3) The extent to which the participant has problems of a personal nature, such as a physical or mental disability or terminal illness in the immediate family, which so intrude on the participant's present and future ability to perform as to raise a presumption that the individual will be unable to perform the obligation incurred.

§ 68.15 When can an NIH LRP payment obligation be discharged in bankruptcy?

Any payment obligation incurred under § 68.13 of this part may be discharged in bankruptcy under Title 11 of the United States Code only if such discharge is granted after the expiration of the seven-year period beginning on the first date that payment is required and only if the bankruptcy court finds that a non-discharge of the obligation would be unconscionable.

§ 68.16 Additional conditions.

(a) When a shortage of funds exists, participants may be funded only partially, as determined by the NIH. However, once an NIH LRP contract has been signed by both parties, the NIH will obligate such funds as necessary to ensure that sufficient funds will be available to pay benefits for the duration

of the period of obligated service unless, by mutual written agreement, the parties specify otherwise.

(b) Additional conditions may be imposed as deemed necessary.

§ 68.17 What other regulations and statutes apply?

Several other regulations and statutes apply to this part. These include, but are not necessarily limited to:

(a) Debt Collection Act of 1982 (31 U.S.C. 3701 note);

(b) Fair Credit Reporting Act (15 U.S.C. 1681 et seq.);

(c) Federal Debt Collection Procedures Act of 1990 (28 U.S.C. 176); and

(d) Privacy Act of 1974 (5 U.S.C. 552a).

Dated: January 16, 2013.

Francis S. Collins,

Director, National Institutes of Health.

Approved: March 27, 2013.

Kathleen Sebelius,

Secretary.

[FR Doc. 2013–07737 Filed 4–4–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 60 and 61

RIN 0906–AA87

National Practitioner Data Bank

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Final rule.

SUMMARY: This final rule revises existing regulations under sections 401–432 of the Health Care Quality Improvement Act of 1986 and section 1921 of the Social Security Act, governing the National Practitioner Data Bank, to incorporate statutory requirements under the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act). The Department of Health and Human Services (HHS) also is removing regulations which implemented the Healthcare Integrity and Protection Data Bank. Section 6403 of the Affordable Care Act, the statutory authority for this regulatory action, was designed to eliminate duplicative data reporting and access requirements between the Healthcare Integrity and Protection Data Bank (HIPDB) (established under section 1128E of the Social Security Act) and the National Practitioner Data Bank (NPDB). It requires the Secretary to establish a transition period to transfer all data in the Healthcare Integrity and Protection Data Bank to the National Practitioner Data Bank, and, once completed, to cease operations of the Healthcare Integrity and Protection Data Bank. Information previously collected and disclosed to eligible parties through the HIPDB will then be collected and disclosed to eligible parties through the NPDB. This regulatory action consolidates the collection and disclosure of information from both data banks into one part of the CFR.

DATES: The effective date of this rule is May 6, 2013.

FOR FURTHER INFORMATION CONTACT: Director, Division of Practitioner Data Banks, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, 5600 Fishers Lane, Room 8–103, Rockville, MD 20857; telephone number: (301) 443–2300.

SUPPLEMENTARY INFORMATION:

I. Background

A. Legal Authorities Governing the Data Banks

The paragraphs below provide a summary of the legal authorities governing the NPDB and the HIPDB.

(1) The Health Care Quality Improvement Act of 1986 (42 U.S.C. 11101 et seq.)

The NPDB was established by the Health Care Quality Improvement Act of 1986 (HCQIA), as amended (42 U.S.C. 11101 et seq.). The HCQIA authorizes the NPDB to collect reports of adverse licensure actions against physicians and dentists (including revocations, suspensions, reprimands, censures, probations, and surrenders); adverse clinical privileges actions against physicians and dentists; adverse professional society membership actions against physicians and dentists; Drug Enforcement Administration (DEA) certification actions; Medicare/Medicaid exclusions; and medical malpractice payments made for the benefit of any health care practitioner. Organizations that have access to this data system include hospitals, other health care entities that have formal peer review processes and provide health care services, state medical or dental boards and other health care practitioner state boards. Individual practitioners may self-query. Information under the HCQIA is reported by medical malpractice payers, state medical and dental boards, professional societies with formal peer review, and hospitals and other health care entities (such as health maintenance organizations).

(2) Section 1921 of the Social Security Act (42 U.S.C. 1396r–2) (Prior to the Passage of the Affordable Care Act)

Section 1921 of the Social Security Act (herein referred to as section 1921), as amended by section 5(b) of the Medicare and Medicaid Patient and Program Protection Act of 1987, Public Law 100–93, and as amended by the Omnibus Budget Reconciliation Act of 1990, Public Law 101–508, expanded the scope of the NPDB. Section 1921 requires each state to adopt a system for reporting to the Secretary certain adverse licensure actions taken against health care practitioners and entities by any authority of the state responsible for the licensing of such practitioners or entities. It also requires each state to report any negative action or finding that a state licensing authority, a peer review organization, or a private accreditation entity had taken against a health care practitioner or health care entity.

Groups with access to this information include all organizations eligible to query the NPDB under the HCQIA (hospitals, other health care entities that have formal peer review and provide health care services, state medical or dental boards, and other health care practitioner state boards), other state licensing authorities, agencies administering government health care programs (including private entities administering such programs under contract), state agencies administering or supervising the administration of government health care programs, state Medicaid fraud control units, certain law enforcement agencies, and utilization and quality control Quality Improvement Organizations (QIOs). Individual health care practitioners and entities may self-query. Information under section 1921 is reported by state licensing and certification authorities, peer review organizations, and private accreditation entities.

Final regulations implementing section 1921 were issued on January 28, 2010 (75 FR 4656). The NPDB began collecting and disclosing section 1921 information on March 1, 2010.

(3) Section 1128E of the Social Security Act (42 U.S.C. 1320a–7e) (Prior to the Passage of the Affordable Care Act)

Section 1128E of the Social Security Act (herein referred to as section 1128E), as added by section 221(a) of the Health Insurance Portability and Accountability Act of 1996, Public Law 104–191, directed the Secretary to establish and maintain a national health care fraud and abuse data collection

program for the reporting and disclosing of certain final adverse actions taken against health care practitioners, providers, or suppliers. This data bank is known as the HIPDB. Section 1128E required Federal and state government agencies and health plans to report to the HIPDB the following final adverse actions: licensing and certification actions; criminal convictions and civil judgments related to the delivery of health care services; exclusions from government health care programs; and other adjudicated actions or decisions. Federal and state government agencies and health plans have access to this information. Individual practitioners, providers, and suppliers may self-query the HIPDB.

The HIPDB began collecting reports in November 1999. Requirements of both HCQIA and section 1921 overlap with the requirements under section 1128E, although each law has unique characteristics, including differences in the types of reportable actions and the types of agencies, entities, and officials with access to information. For example, all three reporting schemes require the reporting of state licensure actions. The HCQIA, however, only requires the reporting of licensure actions taken against physicians and dentists that are based on professional competence or conduct. In contrast, sections 1921 and 1128E do not have a requirement that reportable adverse licensure actions be based on professional competence or conduct and also differ in the types of subjects reported. In addition, sections 1921 and 1128E authorize access to many of the same types of agencies, organizations, and officials. For example, both statutes authorize access by law enforcement agencies, agencies that administer or pay for health care services or programs, and state licensing authorities. Private-sector hospitals and health care service providers are only able to access information reported under the HCQIA and section 1921, but not under section 1128E.

(4) Section 6403 of the Patient Protection and Affordable Care Act of 2010

Section 6403 of the Patient Protection and Affordable Care Act of 2010 (hereinafter referred to as section 6403), Public Law 111–148, amends sections 1921 and 1128E to eliminate duplication between the HIPDB and the NPDB, and requires the Secretary to establish a transition period for transferring data collected in the HIPDB to the NPDB and to cease HIPDB operations. Information previously collected and disclosed through the HIPDB will then be collected and disclosed through the NPDB. No new data elements have been added as a result of section 6403. All actions currently reported in the NPDB and HIPDB will be reported to the NPDB.

All security standards that are currently in place to protect the confidentiality of information in the Data Banks will be retained. HRSA follows the National Institute of Standards and Technology (NIST) security guidelines. More specifically, the Data Bank has extensive operational, management, and technical controls that ensure the security of the system and protect the data in the system. The Data Bank contains information classified under the Privacy Act that is considered personally identifiable information (PII). On an annual basis, the Data Bank conducts a detailed security review process that tests the effectiveness of the security controls to ensure the PII in the system remains safe. Finally, every three years, the Data Bank is Certified and Accredited (C&A) as a requirement to have an Authority to Operate (ATO), in order to function as a Federal system.

The specific amendments section 6403 makes to sections 1921 and 1128E are described in greater detail in the paragraphs below.

Subsection (a) of section 6403 amends section 1128E to require reporting to the NPDB instead of the HIPDB. Subsection (a) also eliminates requirements in section 1128E related to reporting by state agencies; conforms the requirements for reporting Federal licensing and certification actions to those that apply to state agencies under section 1921; provides that the information reported pursuant to section 1128E will be available to the agencies, entities, and officials authorized to access information reported pursuant to section 1921; and authorizes the Secretary to establish reasonable fees for the disclosure of the information, with no exception from the fee for Federal Government agencies. Finally, subsection (a) requires the Secretary, in implementing the amendments to section 1128E, to provide for the maximum appropriate coordination between part B of the HCQIA and section 1921.

Subsection (b) of section 6403 adds to section 1921 the state agency reporting requirements that were eliminated from section 1128E by subsection (a). These state actions, taken against health care practitioners, providers, and suppliers, include state licensing and certification actions, state health care-related criminal convictions and civil judgments, exclusions from government health care programs, and other adjudicated actions or decisions. Subsection (b) also conforms the requirements for reporting state licensing and certification actions to those that apply to Federal agencies under section 1128E and makes amendments to expand the data access provisions of section 1921(b) so that entities that were authorized to access final adverse action information reported to the HIPDB by state agencies under section 1128E will retain access to that information when it is reported to the NPDB under section 1921. Subsection (b) also adds new provisions under section 1921 that are modeled on similar provisions in section 1128E. These new provisions require the Secretary to disclose reported information to a subject of a report and establish other requirements designed to ensure that the information reported pursuant to section 1921 is accurate; authorize the Secretary to establish or approve reasonable fees for the disclosure of information reported pursuant to section 1921; and provide protection against liability in a civil action for entities reporting information as required by section 1921 (so long as such entities have no knowledge of the falsity of the information). Subsection (b) also provides definitions for the following terms: (1) ''State licensing or certification agency;'' (2) ''State law or fraud enforcement agency;'' and (3) ''final adverse action.'' Finally, subsection (b) requires the Secretary, in implementing the amendments to section 1921, to provide for the maximum appropriate coordination with HCQIA and section 1128E.

Subsection (c) of section 6403 amends section 1128C of the Social Security Act regarding the HHS Office of Inspector General's responsibilities with respect to section 1128E by deleting the HHS Office of Inspector General's responsibility to provide for the reporting and disclosure of certain final adverse actions against health care providers, suppliers, or practitioners pursuant to the data collection system established under section 1128E. Subsection (d) establishes requirements for a transition process; authorizes the Department of Veterans Affairs to access, free of charge for one year, information that was formerly reported only to the HIPDB; describes the availability of additional funds for the transition process, if necessary; and includes the effective date for the section.

Effectively, in addition to transferring HIPDB data and operations to the NPDB, section 6403 transfers all section 1128E reporting requirements by state agencies to section 1921, thereby eliminating

duplication in certain state agency reporting requirements under both statutes, while leaving Federal agency and health plan reporting requirements under the authority of section 1128E. Section 6403 also creates a common list of queriers for section 1921 and section 1128E data. There are exceptions to this common querier list. Hospitals and other health care entities, professional societies, and QIOs have access to section 1128E data as well as licensing and certification actions under section 1921, but have no additional access to data as a result of section 6403. By maintaining many of the same reporting requirements and by maintaining different levels of access depending on who is requesting information in section 6403, Congress further indicated its intent that, despite the transition of HIPDB operations to the NPDB, original reporting and querying requirements remain the same to the greatest extent possible, while ensuring the maximum coordination among the three statutes. Section 6403 does not affect reporting requirements or query access under the HCQIA, so existing requirements under the HCQIA for hospitals, other health care entities, professional societies, or medical malpractice payers will not change.

The reporting and querying requirements of sections 1921 and 1128E, as amended by section 6403, are described in greater detail below.

B. Section 1921 as Amended by Section 6403

As amended by section 6403, section 1921 requires each state to have in effect a system of reporting licensure and certification actions taken against a health care practitioner or entity by a state licensing or certification agency. Section 6403 defines a state licensing or certification agency to include state licensing authorities, peer review organizations, and private accreditation entities. Licensing and certification actions include certain adverse actions taken by a state licensing authority as well as any negative action or finding that a state licensing authority, a peer review organization, or a private accreditation entity has concluded against a health care practitioner or entity. Each state also must have in effect a system of reporting information with respect to any final adverse action (not including settlements in which no findings of liability have been made) taken against a health care practitioner, provider, or supplier by a state law or fraud enforcement agency. These final adverse actions include criminal convictions or civil judgments in state court related to the delivery of health care services, exclusions from participation in a government health care program, and any other adjudicated action or decision. In addition, final adverse actions include any licensure or certification action taken against a supplier by a state licensing or certification agency. Section 1921 information is now available to agencies administering government health care programs, including private entities administering such programs under contract; state licensing or certification agencies, and Federal agencies responsible for the licensing and certification of health care practitioners, providers, and suppliers; state agencies administering or supervising the administration of government health care programs; health plans; state law or fraud enforcement agencies; and the U.S. Attorney General and other law enforcement officials as the Secretary deems appropriate. In addition, QIOs, as well as hospitals, professional societies, and other health care entities have access to ''licensure and certification actions'' reported under section 1921. These entities do not have access to ''final adverse actions'' added to section 1921 by section 6403. Potential subjects of section 1921 reports, including health care practitioners, health care entities, providers, and suppliers, may self-query.

C. Section 1128E, as Amended by Section 6403

Section 6403 amends section 1128E to require the Secretary to maintain a national health care fraud and abuse data collection program under this section for the reporting of certain final adverse actions against health care practitioners, providers, and suppliers. The Secretary shall furnish the information collected under section 1128E to the NPDB. Federal Government agencies and health plans are required to report to the NPDB the following final adverse actions: licensing and certification actions; criminal convictions and civil judgments in Federal or state court related to the delivery of health care services; exclusions from government health care programs; and other adjudicated actions or decisions.

The information collected under section 1128E shall be available from the NPDB to all agencies, authorities, and officials which are authorized under the amended section 1921 access provisions. However, under the section 1921 access provisions, hospitals, other health care entities, professional societies, and QIOs are only authorized to receive certain section 1921 information. Individual practitioners, providers, and suppliers may self-query the NPDB to receive section 1128E information.

The table below further illustrates the impact that section 6403 has on current data bank requirements, presenting the requirements for the HCQIA, sections 1921 and 1128E before the passage of section 6403, and the updated requirements after passage of section 6403.

The table is only a summary of the statutory reporting and querying requirements before and after passage of section 6403. All elements in the table, including definitions of terms used, are detailed in various sections of this final rule.

TABLE 1—DATA BANKS STATUTORY REQUIREMENTS BEFORE AND AFTER PASSAGE OF SECTION 6403*

Statutory Requirements before Passage of Section 6403	Reporting/Querying Requirements after Passage of Section 6403
WHO REPORTS?	***WHO REPORTS?***
HCQIA (NPDB) ▪ Medical malpractice payers ▪ Boards of Medical/Dental Examiners ▪ Hospitals and other healthcare entities ▪ Professional societies with formal peer review ▪ Drug Enforcement Administration ▪ Health and Human Services-Office of Inspector General	**HCQIA (NPDB)** ▪ Medical malpractice payers ▪ Boards of Medical/Dental Examiners ▪ Hospitals and other healthcare entities ▪ Professional societies with formal peer review ▪ Drug Enforcement Administration ▪ Health and Human Services-Office of Inspector General
SECTION 1921 (NPDB)	**SECTION 1921 (NPDB)**

TABLE 1—DATA BANKS STATUTORY REQUIREMENTS BEFORE AND AFTER PASSAGE OF SECTION 6403*—Continued

Statutory Requirements before Passage of Section 6403	Reporting/Querying Requirements after Passage of Section 6403
▪ Peer review organizations ▪ Private accreditation organizations ▪ State authorities that license practitioners and entities	▪ Peer review organizations ▪ Private accreditation organizations ▪ State authorities that license or certify practitioners, entities, providers, suppliers ▪ State law or fraud enforcement agencies
SECTION 1128E (HIPDB) ▪ Federal and state government agencies (including state law or fraud enforcement agencies) ▪ Health plans	**SECTION 1128E (NPDB)** ▪ Federal Government agencies ▪ Health plans
WHAT INFORMATION IS REPORTED?	***WHAT INFORMATION IS REPORTED?***
HCQIA (NPDB) ▪ Medical malpractice payments ▪ Adverse licensure actions (physicians/dentists): —revocation, suspension, reprimand, probation, surrender, censure ▪ Adverse clinical privileges actions (primarily physicians/dentists) ▪ Adverse professional society membership (primarily physicians/dentists) ▪ DEA certification actions ▪ Medicare/Medicaid exclusions	**HCQIA (NPDB)** ▪ Medical malpractice payments ▪ Adverse licensure actions (physicians/dentists): —revocation, suspension, reprimand, probation, surrender, censure ▪ Adverse clinical privileges actions (primarily physicians/dentists) ▪ Adverse professional society membership (primarily physicians/dentists) ▪ DEA certification actions ▪ Medicare/Medicaid exclusions
SECTION 1921 (NPDB) ▪ Licensing actions (practitioners and entities): ..... —revocation, reprimand, censure, suspension, probation ..... —any dismissal or closure of the proceedings by reason of surrendering the license or leaving the state or jurisdiction. —any other loss of the license ..... —any negative action or finding by a state licensing authority, peer review organization, or private accreditation entity.	**SECTION 1921 (NPDB)** ▪ Licensing or certification actions (practitioners, entities, providers, and suppliers): —revocation, reprimand, censure, suspension, probation —any dismissal or closure of the proceedings by reason of surrendering the license or leaving the state or jurisdiction —any other loss of, or loss of the right to apply for, or renew a license —any negative action or finding by a state licensing or certification authority, peer review organization, or private accreditation entity ▪ Health care-related state criminal convictions (practitioners, providers, suppliers) ▪ Health care-related civil judgments in Federal or state court (practitioners, providers, suppliers) ▪ Exclusions from government health care programs (practitioners, providers, suppliers) ▪ Other adjudicated actions or decisions (practitioners, providers, suppliers)
SECTION 1128E (HIPDB) ▪ Licensing and certification actions (practitioners, providers, and suppliers). —revocation, reprimand, suspension, censure, ... —any other loss of license, or right to apply for, or renew, a license, whether by voluntary surrender, non-renewability, or otherwise. —any other negative action or finding that is publicly available information. ▪ Health care-related civil judgments in state court (practitioners, providers, suppliers). ▪ Exclusions from government health care programs (practitioners, providers, suppliers). ▪ Other adjudicated actions or decisions (practitioners, providers, suppliers).	**SECTION 1128E (NPDB)** ▪ Federal licensing/certification actions (practitioners, providers, and suppliers): —revocation, reprimand, censure, suspension, probation —any dismissal or closure of the proceedings by reason of surrendering the license or leaving the state or jurisdiction —any other loss of, or right to apply for, or renew, a license, whether by voluntary surrender, non-renewability, or otherwise —any negative action or finding that is publicly available information ▪ Health care-related civil judgments in Federal or state court (practitioners, providers, suppliers) ▪ Health care-related Federal or state criminal convictions (practitioners, providers, suppliers) ▪ Exclusions from government health care programs (practitioners, providers, suppliers) ▪ Other adjudicated actions or decisions (practitioners, providers, suppliers)
WHO CAN QUERY?	***WHO CAN QUERY?***
HCQIA (NPDB)	**HCQIA (NPDB)**

TABLE 1—DATA BANKS STATUTORY REQUIREMENTS BEFORE AND AFTER PASSAGE OF SECTION 6403*—Continued

Statutory Requirements before Passage of Section 6403	Reporting/Querying Requirements after Passage of Section 6403
▪ Hospitals ▪ Other health care entities with formal peer review ▪ Professional societies with formal peer review ▪ Boards of Medical/Dental Examiners ▪ Other health care practitioner state licensing boards ▪ Plaintiff's attorney/pro se plaintiffs (limited circumstances) ▪ Health care practitioners (self-query) ▪ Researchers (statistical data only)	▪ Hospitals ▪ Other health care entities with formal peer review ▪ Professional societies with formal peer review ▪ Boards of Medical/Dental Examiners ▪ Other health care practitioner state licensing boards ▪ Plaintiff's attorney/pro se plaintiffs (limited circumstances) ▪ Health care practitioners (self-query) ▪ Researchers (statistical data only)
SECTION 1921 (NPDB) ▪ Hospitals and other health care entities (HCQIA) ▪ Professional societies with formal peer review ▪ Quality Improvement Organizations ▪ State licensing agencies that license practitioners and entities ▪ Agencies administering government health care programs, or their contractors ▪ State agencies administering government health care programs ▪ State Medicaid fraud control units ▪ U.S. Comptroller General ▪ U.S. Attorney General and other law enforcement ▪ Health care practitioners/entities (self-query) ▪ Researchers (statistical data only)	**SECTION 1921 and SECTION 1128E (NPDB)** ▪ Hospitals and other health care entities (HCQIA)** ▪ Professional societies with formal peer review** ▪ Quality Improvement Organizations** ▪ State licensing or certification agencies that license or certify practitioners, entities, providers, or suppliers ▪ Agencies administering (including those providing payment for services) government health care programs and their contractors ▪ State agencies administering government health care programs ▪ Federal agencies that license or certify practitioners, providers, suppliers ▪ Health plans ▪ State law or fraud enforcement agencies (including state medicaid fraud control units) ▪ U.S. Comptroller General ▪ U.S. Attorney General and other Federal law enforcement ▪ Health care practitioners, entities, providers, suppliers (self-query) ▪ Researchers (statistical data only).
SECTION 1128E (HIPDB) ▪ Federal and state government agencies ▪ Health plans ▪ Health care practitioners/providers/suppliers (self-query) ▪ Researchers (statistical data only)	

* For NPDB requirements, the term ''practitioners'' is used throughout this table to mean ''practitioners, physicians, and dentists.''
** Under Section 1921, these entities only have access to reported licensing or certification actions, which is consistent with these entities' access prior to enactment of the Affordable Care Act.

D. Maximum Coordination When Implementing Section 6403

Sections 6403(a)(3) and 6403(b)(4) require the Secretary to provide for the maximum appropriate coordination among HCQIA, section 1921, and section 1128E when implementing the provisions of section 6403. We have made significant efforts to develop this final rule in a manner that minimizes the burden on reporters. Reporters previously responsible for reporting adverse actions to both the NPDB and HIPDB only needed to submit one report per action, provided that reporting was done through the Department's web-based system that sorted the appropriate actions into the HIPDB, the NPDB, or both. Similarly, under the revised regulations, reporters will only need to submit one report per action.

Congress's mandate that the Secretary provide for the maximum appropriate coordination among the statutes makes it necessary, in certain cases, to make slight modifications when combining sometimes overlapping statutory requirements. These instances are described in the paragraphs below, and in the discussion of the final regulatory definitions.

E. Terms Used To Describe Subjects of Reports Under Sections 1921 and 1128E

We clarified statutory language used to describe report subjects in several ways. First, we use the term ''health care practitioner'' throughout these regulations to refer to physicians, dentists, and other health care practitioners. The HIPDB definition of ''health care practitioner'' includes physicians and dentists. However, prior to implementation of this regulation, the NPDB definition of ''health care practitioner'' specifically excluded physicians and dentists. Therefore, when combining the HIPDB and NPDB definition in this rule, a decision had to be made about which definition to use. For the purposes of clarity, HRSA has decided to use the HIPDB definition. This decision does not expand or contract reporting requirements and does not make any substantive changes to the rule, but simply affects how certain subjects are described in the regulation. Further, this is consistent with how HRSA uses the term in guidance documents. We continue to define and use the terms ''physician'' and ''dentist'' in the Rule when there are specific references to physicians and dentists.

Second, we clarified statutory language with respect to report subjects by consistently using the term ''entity, provider, and supplier'' in referring to section 1921 entity report subjects. Both original and amended section 1921 reporting requirements include certain adverse actions taken against a ''health care practitioner or entity,'' and NPDB regulations use the HCQIA definition of ''health care entity'' to define the range of these report subjects. It is clear from the context of section 6403 that the use of the term ''entity'' also includes ''supplier'' subjects. Specifically, section 6403(b), which added the disclosure and correction provision in section 1921(d), refers only to ''health care practitioner'' and ''entity'' report subjects. It is not reasonable to conclude that Congress intended to prevent providers and suppliers from having access to their own reports or being able to dispute a report, while giving that ability to health care practitioners and entities. Although the provision only uses the terms practitioner and entity, it must be read broadly to keep the congressional intent of not making significant changes to current reporting and querying requirements. Therefore, we apply this provision to all section

1921 report subjects, including health care practitioners, entities, providers, and suppliers.

Finally, the proposed rule sometimes refers to ''practitioner, provider, and supplier'' as one grouping. The manner in which the regulation defines supplier may be read to include physicians and dentists. In the final rule, where physicians and dentists are specified, but other suppliers are not, it is intended that other suppliers are not included in those instances. Where suppliers are mentioned along with physicians and dentists, the intent is not to imply that suppliers do not include physicians and dentists, but that all terms were included for the sake of clarity.

F. Sanction Authority

HIPDB regulations include sanctions against Federal and state agencies and health plans for failure to report as required. For Federal and state government agencies, the Secretary provides for publication of a public report that identifies those agencies that have failed to report information as required. Health plans that fail to report information as required under section 1128E are subject to a civil money penalty of up to $25,000 for each action not reported. While section 6403 transfers state agency reporting requirements from section 1128E to section 1921, we plan to maintain existing sanction authority (publication of a public report) for those state agencies that are required to report licensure and certification actions, exclusions from government health care programs, criminal convictions and civil judgments in a state court, and other adjudicated actions or decisions. Further, we plan to maintain existing sanction authority, as stated above, and which currently exists in section 1128E, for those Federal agencies that fail to report. These sanctions are currently part of the agency's compliance plan, and we are attempting to maintain consistency between current and future Data Bank operational policy.

G. Authorization Dates for Collecting Reports

The authorization dates for collecting adverse actions under section 1921 and section 1128E are based on the original legislation for the requirements and are unchanged by the passage of section 6403. Amendments made by section 6403 represent a reorganization of existing statutory requirements and not an imposition of new actions. Therefore, the passage of section 6403 does not affect reporters' obligations to report action back to the dates currently in use for the system. Actions taken by state agencies transferred from section 1128E to section 1921 will retain their original authorization dates.

II. Summary of the Proposed Rule

The proposed regulation published on February 15, 2012 (77 FR 9138) amended the following sections of the regulations.

60.1 The National Practitioner Data Bank

The proposed rule amended this section by incorporating the statutory provisions for section 1128E of the Social Security Act.

60.2 Applicability of These Regulations

The proposed rule amended this section by revising the reporting requirements to include those organizations and agencies required to report under section 1921 and section 1128E (both as amended by section 6403).

60.3 Definitions

In the proposed rule, we incorporated existing definitions from the HIPDB regulations and added new statutory definitions created by section 6403. We also modified existing regulatory definitions by combining similar regulatory definitions for the same term where NPDB and HIPDB terms overlapped and were inconsistent, or deleted terms where a combination would not make sense. For example, the term ''Act'' was deleted because it was vague and could not be used to distinguish between the three statutes that now govern the operation of the NPDB. We believe this approach is consistent with the mandate that the Secretary provide for the maximum appropriate coordination among the HCQIA, section 1921, and section 1128E. The proposed rule also clarified new statutory definitions by providing additional examples of the scope of the definitions.

As a result, we added the following new terms to this section, which are in the current HIPDB regulations: ''civil judgment,'' ''criminal conviction,'' ''exclusion,'' ''Federal Government agency,'' ''health care provider,'' ''health care supplier,'' ''health plan,'' ''other adjudicated actions or decisions,'' ''state law or fraud enforcement agency,'' and ''state licensing or certification agency.''

In addition to the new terms we added in this section, we also slightly amended the definitions of the following existing terms to ensure the maximum appropriate coordination among requirements for the HCQIA, and sections 1921 and 1128E of the Social Security Act: ''board of medical examiners, or board,'' ''health care entity,'' ''health care practitioner, licensed health care practitioner, licensed practitioner, or practitioner,'' ''hospital,'' ''negative action or finding,'' ''peer review organization,'' ''physician,'' ''private accreditation entity,'' and ''voluntary surrender of license or certification.''

In addition to the definitions we have added or clarified, we also eliminated the term ''Act'' from section 60.3. We chose this approach to avoid confusion when referencing the different statutes governing NPDB operations. NPDB regulations currently define ''Act'' as the Health Care Quality Improvement Act of 1986, title IV of Public Law 99–660, as amended. HIPDB regulations define ''Act'' as the Social Security Act. We instead reference each of these statutes (as well as other governing statutes) by name where they appear in the regulations.

We also used the NPDB definition for the term, ''state,'' as it relates to all requirements under the HCQIA and sections 1921 and 1128E.

60.4 How Information Must Be Reported

The proposed rule sought to amend this section by changing the reference to ''§ 60.11'' to read ''§ 60.12'' and including references to the newly added §§ 60.10, 60.11, 60.13, 60.14, 60.15, and 60.16. The reference to reporting to the Board of Medical Examiners was also removed.

60.5 When Information Must Be Reported

The proposed rule sought to amend this section of the existing NPDB regulations by:

a. Revising the introductory text of this section to include references to the newly added §§ 60.10, 60.13, 60.14, 60.15, and 60.16 and redesignated §§ 60.11 and 60.12;

b. Adding the August 21, 1996, legacy reporting date for section 1128E actions; and

c. Removing paragraphs (a)—(d) and replacing them with a list of reportable actions. This list reflects the combination of reporting categories from the NPDB and the HIPDB regulations.

The proposed rule brought the HIPDB reporting time frame in line with the NPDB and eliminated references from the current HIPDB regulation to reporting by the close of an entity's next monthly reporting cycle. The proposed rule also eliminated from the current NPDB regulation the requirement for

reporting within a 15-day window for those entities that have a dual obligation to report to a state authority. Thus, all reports must be made within 30-calendar days from the date the final adverse action was taken. This rule also sought to clarify the state reporting obligations for persons or entities responsible for submitting malpractice payments (§ 60.7), negative actions or findings (§ 60.11), and adverse actions (§ 60.12). Reports for these three categories are submitted directly to the NPDB and a copy of the report must be mailed to the appropriate state licensing or certification agency. This has been the operational practice of the NPDB since 1990 and fulfills the statutory state reporting obligation for these reporters.

60.6 Reporting Errors, Omissions, Revisions or Whether an Action is on Appeal

The proposed rule sought to amend this section by:

a. Revising the title to include reporting of whether an action is on appeal. This information currently must be reported for final adverse actions specified in HIPDB regulations;

b. Revising the first and last sentences in paragraph (b) to include the requirement to report revisions to actions for all licensure and certification actions, criminal convictions, civil judgments, exclusions, and other adjudicated actions or decisions. The HIPDB regulations require reporting of revisions to these actions;

c. Revising the third sentence of paragraph (b) to include the requirement to report when an action is on appeal for licensure and certification actions, criminal convictions, civil judgments, exclusions, and other adjudicated actions; and

d. Adding a new sentence at the end of paragraph (a) and new paragraphs (c) and (d) to clarify current data bank policy regarding notifying subjects of a report and the steps subjects may take to ensure the information reported is accurate. These clarifications generally are included in HIPDB regulations, but the same policy has applied to the NPDB as well.

60.7 Reporting medical malpractice payments. (The proposed rule made no changes to this section.)

60.8 Reporting Licensure Actions Taken by Boards of Medical Examiners

The proposed rule sought to amend this section by revising the reference to ''§ 60.11'' in the last sentence of paragraph (c) to read ''§ 60.12.'' This change reflects the fact that 60.11 was redesignated as § 60.12 in these proposed rules. The proposed rule also added ''Individual Tax Identification Number (ITIN)'' to § 60.8(b)(4) after the word Social Security Number.

60.9 Reporting Licensure and Certification Actions Taken by States

The proposed rule amended § 60.9 to reflect the changes made by section 6403 to the section 1921 licensure action reporting requirements by state agencies. The title of this section was revised to include licensure and certification actions, as required under section 6403(b)(1)(A)(i). The term ''certification'' has two distinct meanings in both the NPDB and HIPDB regulations. First, in both sets of regulations, ''certification'' is related to licensure. Licensure includes certification and other forms of authorization to provide health care services, and, based on their individual laws and requirements, states may ''license,'' ''certify,'' or ''register'' certain types of health care practitioners, health care entities, providers, or suppliers. For example, states may certify nurse's aides. Second, in section 1128E and the HIPDB regulations, the term ''certification'' is also used to refer to certification of a health care practitioner, provider, or supplier to participate in a government health care program. In this context, certification includes certification agreements and contracts for participation in a government health care program. State certification actions such as termination of a hospital's Medicaid participating provider agreement or contract are now being reported to the NPDB under this part.

The proposed rule also modified paragraphs (a) and (b) to reflect the range of subjects reported under this section to include health care practitioners, health care entities, providers, and suppliers. In addition, the proposed rule amended paragraphs (a)(1) through (a)(4) to reflect changes to those reporting requirements made by section 6403(b)(1)(A), which intended to harmonize state licensure and certification action reporting requirements with Federal licensure and certification action reporting requirements under section 1128E. To reflect the fact that section 6403 transferred state licensure and certification action reporting requirements from section 1128E to section 1921, the proposed rule made the following changes to ensure that the original reporting requirements from the HIPDB regulations remain unchanged. First, we amended language in paragraphs (a)(1) through (4) to clarify the range of reportable licensure and certification actions with respect to a license, certification agreement, or contract for participation in government health care programs. Second, in paragraph (c)(4)(ii), which was previously a reserved field, we added a data element for the date of any appeal. Third, we added paragraph (e) to incorporate the sanctions for failure to report that were included in the HIPDB regulations for state licensure and certification actions. Finally, we are also adding ''Individual Tax Identification Number (ITIN)'' to § 60.9(b)(1)(ii) after the word Social Security Number.

60.10 Reporting Licensure and Certification Actions Taken by Federal Agencies

The proposed rule redesignated § 60.10 as § 60.11, and added a new § 60.10 to implement the reporting requirements for Federal licensure and certification agencies. These agencies must report to the NPDB the following final adverse actions that are taken against a health care practitioner, provider, or supplier (regardless of whether the final adverse action is the subject of a pending appeal):

- Formal or official actions, such as revocation or suspension of a license or certification agreement or contract for participation in government health care programs (and the length of any such suspension), reprimand, censure, or probation;
- Any dismissal or closure of the proceedings by reason of the health care practitioner, provider, or supplier surrendering their license or certification agreement or contract for participation in government health care programs, or leaving the state or jurisdiction;
- Any other loss of the license or loss of the certification agreement or contract for participation in a government health care program, or the right to apply for, or renew, a license or certification agreement or contract of the health care practitioner, provider, or supplier, whether by operation of law, voluntary surrender, nonrenewal (excluding non-renewals due to nonpayment of fees, retirement, or change to inactive status), or otherwise; and
- Any other negative action or finding by such Federal agency that is publicly available information.

Further, the proposed rule substituted the acronym ''ITIN'' in place of the word ''Individual Tax Identification Number'' in § 60.10(b)(1)(ii).

60.11 Reporting Negative Actions or Findings Taken by Peer Review Organizations or Private Accreditation Entities. [Redesignated]

The proposed rule redesignated § 60.11 as § 60.12 and added redesignated § 60.10 as § 60.11. In accordance with the changes to the scope of ''entity'' report subjects required by section 6403, the proposed rule amended paragraph (a) of this section to include the reporting of health care practitioners, health care entities, providers, and suppliers. While peer review organizations will continue to report negative actions or findings taken against health care practitioners, private accreditation entities are required to report actions taken against health care entities, providers, or suppliers. Paragraph (a) is revised to reflect that the reporting entity, (i.e., peer review organization or private accreditation entity) not the state, must submit reports directly to the NPDB and then provide a copy of the report to the appropriate state licensing or certification authority by mail. The remaining paragraphs (b)–(d) are accordingly modified to reflect this reporting scheme.

60.12 Reporting Adverse Actions Taken Against Clinical Privileges. [Redesignated]

The proposed rule redesignated § 60.12 as § 60.17 and added redesignated § 60.11 as § 60.12. As done with § 60.11, the reporting scheme under paragraph (a) is revised to reflect that health care entities send reports directly to the NPDB and provide a copy of the report to the State Board of Medical Examiners.

Further, the proposed rule slightly modified the heading of § 60.12(a) to read ''Reporting by Health Care Entities to the NPDB.''

60.13 Reporting Federal or State Criminal Convictions Related to the Delivery of a Health Care Item or Service

The proposed rule redesignated § 60.13 as § 60.18, and added a new § 60.13 to implement the requirements of section 6403. Under this provision, Federal and state prosecutors are required to report criminal convictions against health care practitioners, providers, or suppliers related to the delivery of a health care item or service (regardless of whether the conviction is the subject of a pending appeal).

60.14 Reporting Civil Judgments Related to the Delivery of a Health Care Item or Service

The proposed rule redesignated § 60.14 as § 60.19, and added a new § 60.14 to implement the requirements of section 6403. Under this provision Federal and state attorneys and health plans must report civil judgments against health care practitioners, providers, or suppliers related to the delivery of a health care item or service (regardless of whether the civil judgment is the subject of a pending appeal).

60.15 Reporting Exclusions From Participation in Government Health Care Programs

The proposed rule redesignated § 60.15 as § 60.20, and added a new § 60.15 to implement the requirements of section 6403. Under this provision, Federal Government agencies and state law and fraud enforcement agencies must report health care practitioners, providers, and suppliers excluded from participating in government health care programs, including exclusions resulting from a settlement that is not reported because no findings or admissions of liability have been made (regardless of whether the exclusion is the subject of a pending appeal).

60.16 Reporting Other Adjudicated Actions or Decisions

The proposed rule redesignated § 60.16 as § 60.21, and added a new § 60.16 to implement the requirements of section 6403. Under this provision, Federal Government agencies, state law and fraud enforcement agencies, and health plans must report other adjudicated actions or decisions as defined in § 60.3 related to the delivery, payment or provision of a health care item or service against health care practitioners, providers, and suppliers (regardless of whether the other adjudicated action or decision is subject to a pending appeal).

60.17 Information Which Hospitals Must Request From the National Practitioner Data Bank [Redesignated]

The proposed rule redesignated § 60.12 as § 60.17.

60.18 Requesting Information From the National Practitioner Data Bank [Redesignated]

The proposed rule redesignated § 60.13 as § 60.18. The proposed rule sought to amend § 60.18, paragraph (a) of the existing NPDB regulations to clarify to whom information under the HCQIA as well as the amended sections 1921 and 1128E components of the NPDB would be made available by:

a. Redesignating § 60.13 as § 60.18 to implement the requirements of section 6403;

b. Revising the reference to ''§ 60.11'' in paragraph (a)(1) to read ''§ 60.12;''

c. Revising the reference to ''§ 60.12'' in paragraph (a)(1)(v) to read ''§ 60.17;''

d. Adding the references to include §§ 60.10, 60.11, 60.13, 60.14, 60.15, and 60.16 in paragraph (a)(2);

e. Revising paragraph (a)(2)(i) to include the following language in parentheses after the word administering: ''including those providing payment for services;''

f. Replacing the text in paragraphs (a)(2), (ii), (iv), (v), (vi), and (vii) to reflect the revised list of entities which may receive information reported under §§ 60.9, 60.10, 60.11, 60.13, 60.14, 60.15 and 60.16; and

g. Inserting paragraph (a)(2)(viii).

Based on section 6403 amendments, state licensing or certification agencies and Federal agencies responsible for the licensing and certification of health care practitioners, providers and suppliers are authorized to query the NPDB under section 1921 and 1128E. We understand the statutory language to limit query access to those state licensing and certification agencies that license or certify health care practitioners, entities, providers, or suppliers. These agencies would include only authorities of the state responsible for licensure or certification and would exclude peer review organizations and private accreditation entities. Such an interpretation of the statutory language is consistent with the goal of maintaining existing NPDB and HIPDB reporting and querying requirements to the greatest extent possible.

Consistent with section 6403 language, hospitals and other health care entities, professional societies, and QIOs will have access to section 1921 information reported in §§ 60.9 and 60.11, and section 1128E information reported in §§ 60.10, 60.13, 60.14, 60.15, and 60.16. Access to the section 1921 information for these groups was not affected by the passage of section 6403. Section 6403 expands the access that these groups have with respect to Federal information under section 1128E.

60.19 Fees Applicable to Requests for Information [Redesignated]

The proposed rule amended redesignated § 60.19(a) to reflect, based on section 6403 amendments, the full range of subjects that will be sent a copy of a report submitted about them.

60.20 Confidentiality of National Practitioner Data Bank Information [Redesignated]

The proposed rule slightly amended redesignated § 60.20 so that it reflects the limitations on disclosure provisions based on current NPDB and HIPDB regulatory language. These confidentiality requirements would apply to all information obtained from the NPDB.

60.21 How To Dispute the Accuracy of National Practitioner Data Bank Information [Redesignated]

The dispute process for the NPDB and the HIPDB is identical; however, HIPDB regulations currently provide a more detailed account of the process than do the NPDB regulations. Therefore, the proposed rule amended this section to include the HIPDB regulatory provisions for disputing the accuracy of data bank information.

60.22 Immunity.

Section 6403 added a provision to section 1921 that provides reporters of NPDB information immunity from liability in a civil action filed by the subject of a report, unless the individual, entity, or authorized agent submitting the report has actual knowledge of the falsity of the information contained in the report. HIPDB regulations also contain a similar immunity provision. The proposed rule added this provision, which will apply to all individuals who, and entities and authorized agents that, report information to the NPDB.

III. Summary and Response to Public Comments

The proposed rule set forth a 60-day public comment period, ending April 16, 2012. HRSA received 11 public comments from several private citizens, a health care entity, a state department of public health, a consumer rights advocacy group, a health care accrediting body, and several national associations representing physicians, nurses, health insurers, and health plans. None of the public comments opposed the merger of the HIPDB with the NPDB. Four out of the 11 comments did not request any changes or clarifications and wrote expressly to commend HRSA for taking this step to improve efficiency and reduce duplication of effort by the government. The remaining seven comments touched upon the following issues: definitions (§ 60.3), the scope of the Secretary's access to documents related to private accreditation actions (§ 60.11), due process requirements for clinical privilege actions (§ 60.12), clarification on reporting civil judgments (§ 60.14), query fees (§ 60.19), and the confidentiality of NPDB information (§ 60.20).

Set forth below is an overview of these comments and our responses by section number of the proposed rule.

Definitions (§ 60.3)

1. Health Care Entity, Health Care Provider, and Health Care Supplier

Comment: One commenter requested that HRSA eliminate redundant and or conflicting definitions for health care provider, supplier, and entity. This commenter specifically urged HRSA to ''establish clear and explicit definitions and criteria for determining the subjects of private accreditation entity reporting.''

Response: Accreditation entities should report only those organizations or business entities that they accredit and that meet the definition of entity, supplier, or provider. Our intention is not to expand who is subject to accreditation entity reporting. These definitions have not proven to be problematic in the past and we believe that the definitions for provider, supplier and entity are well-defined.

Comment: Another commenter also required clarification regarding our usage of the term ''entity'' in a chart in the proposed rule and raised concern over whether HRSA intended to expand the scope of who may query the Data Bank by not providing a specific definition.

Response: HRSA has provided a definition for ''health care entity,'' which is contained in Title IV of HCQIA and was carried over into the proposed rule. The proposed rule has not introduced any new categories of queriers. The section of the chart in question shows that entities could self-query under Section 1921 before the passage of section 6403, and also shows that entities have that same ability after the passage of section 6403.

2. Negative action or finding

Comment: HRSA specifically invited comments on the definition of ''negative action or finding'' in the proposed rule because this was a new definition resulting from the merger of the HIPDB definition with the NPDB definition. We received only two comments. One commenter requested a more detailed definition to avoid inconsistent reporting, while the other commenter requested that the definition not change without a separate rulemaking. The former commenter suggested revising the definition for negative action or finding to read, ''* * * any action or finding which in any way restricts a subject's ability to practice or engage in business or which a reasonable person would interpret as reflecting criticism in any way on the subject even if the subject's ability to practice or engage in business is not affected. This includes reprimands, letters of concern, consent orders, settlement agreements and any other similar item regardless of what it is called.''

Response: HRSA acknowledges that a change in the definition of negative action or finding could have wide-spread implications. We do not believe that we received sufficient comments to warrant a change to the definition at this time. We also acknowledge that additional guidance on the application of this definition would be useful, in particular as the definition pertains to Federal or state licensing or certification authorities. While licensure actions such as revocation, suspension, probation, reprimand or censure that are the result of formal proceedings are clearly understood to be universally reportable, state laws determine how each state defines any additional negative action or finding. Each state must be prepared to justify their decisions, supported by state law, to report or decline to report these actions by referencing specific state statutes. Further, concerning the use of consent agreements or other vehicles through which a board takes formal action, it is our policy that the vehicle itself (i.e., consent agreement) does not make an action reportable or not. Rather, we look at the action taken. For example, if a board issues a reprimand in a consent agreement, the reprimand is reportable. Likewise, if a board issues a consent agreement and orders a person to pay an administrative fine but does not take any other actions, and the state law does not define this as a negative action or finding, this action is not reportable.

3. Peer review organization

Comment: One commenter requested that the definition for ''peer review organization'' be modified to remove the exclusion for Medicare Quality Improvement Organizations (QIOs). This commenter stated that excluding QIOs from reporting to the NPDB ''* * * is contrary to the statute [Section 1921] these proposed regulations are intended to implement.'' The argument for changing this definition hinges upon the use of the phrase ''any peer review organization'' in the statute. This commenter stated that, according to the statutory definition, a QIO is a kind of ''peer review organization'' and should not

have been excluded from reporting to the NPDB.

Response: The issue regarding reporting requirements for QIOs was last addressed in a separate rulemaking that was published in the **Federal Register** on March 21, 2006 (71 FR 14135). At that time we invited comments related to the exemption of QIOs from reporting under Section 1921 and received four comments supporting this exemption and only one comment against this exemption. The final rule was published on January 28, 2010 (75 FR 4656), and the rationale for maintaining the exemption was explained in the preamble of that rule. Under the current rulemaking, specific comments were not elicited on this definition because it is not a new definition that resulted from the merger. Therefore, we find that this comment falls outside the scope of this rulemaking.

4. Other adjudicated actions or decisions

Comment: One commenter requested that HRSA clarify the definition for ''Other adjudicated actions or decisions'' to exclude personnel terminations that are made for administrative or business reasons that are unrelated to health care fraud or abuse or quality of care. According to this commenter, some states and the Centers for Medicare & Medicaid Services (CMS) have mandated a due process mechanism for practitioners in situations where a health plan may have terminated contracts for business reasons (e.g., a health plan ceases operations in a certain geographic area and terminates provider contracts in that region). The commenter feels the current definition could be interpreted to require reporting to the NPDB because of the existence of a due process mechanism.

Response: HRSA agrees with this commenter and has provided examples of business or administrative terminations that are excluded from this definition in the text of the final rule.

5. Professional review action

Comment: One commenter requested that HRSA revise the definition of ''professional review action'' under subsection (d)(4) to insert the word ''physician'' before the term ''health care practitioner'' when talking about the class of members. This request stems from a concern that leaving out this term might suggest that physicians are not excluded under this subsection because it is inconsistent with our practice throughout the proposed rule of spelling out the term ''practitioner'' when talking about the full range of providers subject to the NPDB regulations.

Response: HRSA made the decision to use the term ''health care practitioner'' to be inclusive of physicians and dentists. Therefore, there is no need to add the term ''physician'' to the referenced text.

6. State Law or Fraud Enforcement Agency

Comment: One commenter requested that HRSA revise the proposed definition for ''state law or fraud enforcement agency'' to exclude state agencies administering a government health care program. This commenter specifically worries that HRSA is broadening the scope of the NPDB to include actions that may not be attributable to fraudulent activity and is trying to expand the class of queriers.

Response: All state actions under Section 1128E were transferred to Section 1921 with the passage of section 6403 of the Affordable Care Act. State agencies administering a government health care program were already included under Section 1921 as reporters and queriers prior to the passage of section 6403. Thus these agencies do not constitute a new group of reporters or queriers. To ensure that this group continues to have the same reporting requirements it has always had, we included it under the definition of state law or fraud enforcement agency because the state agencies carry out investigative functions.

Reporting Negative Actions or Findings Taken by Peer Review Organizations or Private Accreditation Entities (§ 60.11)

Comment: One commenter requested that HRSA establish a clear scope, purpose, and limitation on the access the Secretary has to documents related to private accreditation actions.

Response: Access to documents by the Secretary or Secretary's designee in this section pertains solely to assuring compliance with NPDB reporting requirements. Thus, the authority to request documents is limited to the purpose of ensuring proper reporting of peer review and accreditation actions and we believe that such scope is clearly defined. The Secretary has similar access to documents related to other actions.

Reporting Adverse Actions Taken Against Clinical Privileges (§ 60.12)

Comment: One commenter requested that additional regulatory language be added to this section to require a due process mechanism for advanced practice registered nurses and other health care practitioners to ensure that these practitioners are afforded due process rights and procedures equal to those afforded physicians. This commenter suggested adding the following language: ''(d) Exception. Notwithstanding the foregoing, no adverse action taken against the clinical privileges of any health care practitioner shall be reported unless the health care practitioner received a due process hearing before adverse action was taken.''

Response: As indicated in the proposed rule, the current regulations governing the NPDB that were not modified by section 6403 of the Affordable Care Act are not subject to review and comment. The reporting requirements for clinical privileges continue to fall under Title IV of the HCQIA and were not modified by section 6403. Therefore, this comment falls outside the scope of this rulemaking.

Reporting Civil Judgments Related to the Delivery of a Health Care Item or Service (§ 60.14)

Comment: One commenter requested clarification regarding the requirement that health plans must report civil judgments against health care practitioners, providers, or suppliers related to the delivery of a health care item or service. This commenter noted that during the course of a health plan's credentialing processes, the plan may become aware of civil judgments against a practitioner to which the health plan was not a party. The commenter specifically requests that the reporting requirement specify that health plans report only those civil judgments resulting from cases involving the health plan.

Response: Health plans are required to report only those civil judgments to which they are a party. Health plans and other users of the NPDB may notify us if they identify actions that may not have been reported.

Fees Applicable to Requests for Information (§ 60.19)

Comment: Two commenters requested clarification on whether query fees would be raised by the merger of the HIPDB with the NPDB.

Response: Currently, each traditional query costs the querier $4.75 per data bank. Self-queries are $8.00 and Continuous Query enrollments are $3.25 per data bank per year. Once the HIPDB and NPDB are consolidated, queriers who were authorized to query both data banks will need to pay only one single fee instead of two fees. Currently, there are no plans to raise these query fees. To the extent that the fees are changed in

the future, the Department will announce such changes in the **Federal Register**.

Confidentiality of National Practitioner Data Bank information (§ 60.20)

Comment: Two commenters asked HRSA to describe to what extent NPDB confidentiality would be protected and whether state Freedom of Information Acts (FOIA) would apply to the information contained in the NPDB. Another commenter asked HRSA to revise language in this section to strike the phrase ''from its own files to create such reports'' regarding the disclosure of information by a party under applicable state or Federal law. This third commenter expressed concerns that this inserted language might invite researchers and others to seek out the reporting entity to ask for information from the entities' own files and felt that the proposed change was ''superfluous''.

Response: Information reported to the NPDB is considered confidential, and access to and use of the information is prescribed by the three statutes that govern the NPDB. As stated in § 60.20, ''Persons and entities receiving information from the NPDB, either directly or from another party, must use it solely with respect to the purpose for which it was provided.'' Both improper use and access to NPDB information may result in a civil monetary penalty that is currently set at up to $11,000 for each violation. The Privacy Act also protects the contents of Federal records on individuals from disclosure without the individual's consent, unless the disclosure is for a routine use of the system of records as published annually in the **Federal Register**. The published routine uses of NPDB information, which are based on the laws and the regulations under which the NPDB operates, do not allow disclosure to the general public. Given these statutory restrictions on NPDB information, NPDB information is not releasable through FOIA.

The confidentiality provisions prohibit the release of the report submitted to the Data Bank. These provisions, though, do not apply to the original documents or records from which the reported information is obtained. The NPDB's confidentiality provisions do not impose any new confidentiality requirements or restrictions on those documents or records. Thus, the confidentiality provisions do not bar or restrict the release of the underlying documents, or the information itself, by the entity taking the adverse action or making the payment in settlement of a written medical malpractice complaint or claim. For this reason we inserted clarifying language in § 60.20, which already existed in the HIPDB regulations, stating that an entity is free to release information ''from its own files'' provided that such disclosure is otherwise permitted by state and Federal law.

This provision allows the disclosure of information used to create an NPDB report, consistent with other legal requirements, however it does not permit the release of the NPDB report itself. So, for instance, if a state FOIA law requires the release of records, while it may require the release of the records underlying the report, it would not permit the release of the NPDB report itself.

Comment: One commenter raised concern over whether Tax Identification Numbers (TINs) would be viewable on NPDB query reports.

Response: Social Security Numbers and TINs are masked and not viewable on query reports requested by authorized entities. This is done to protect health care practitioners and entities from potential identity theft or misuse of this sensitive information.

IV. Summary of Revisions in the Final Rule

Based on our review and response to HHS and public comments, and on the discretionary authority granted to the Department under section 6403 of the Affordable Care Act, we have made the following revisions to the proposed regulations.

Definitions. (§ 60.3)

We are revising the definition of ''health care practitioner, licensed health care practitioner, licensed practitioner, or practitioner'' to include physicians and dentists.

We are revising the definition of ''other adjudicated actions or decisions'' to include examples of non-reportable contract terminations.

Confidentiality of National Practitioner Data Bank information. (§ 60.20)

We modified language in this section to clarify that a Data Bank report itself may not be disclosed, except as permitted by §§ 60.17, 60.18, and 60.21. The final rule now states ''The Data Bank report may not be disclosed, but nothing in this section will prevent the disclosure of information by a party from its own files used to create such reports where disclosure is otherwise authorized under applicable state or Federal law.''

How to Dispute the Accuracy of National Practitioner Data Bank information. (§ 60.21)

We slightly modified the language in section (b)(1) and (c)(1) to allow for procedural changes as a result of new technologies. Subjects currently dispute a report or request a review of a disputed report online, rather than in writing. We changed the phrase ''in writing'' to ''in the format as determined by the Secretary.'' In addition, to add clarity, in section (c) we changed the phrase ''Procedures for requesting a Secretarial review'' to ''Procedures for requesting a review of a disputed report.''

V. Regulatory Impact Statement

A. Regulatory Analysis

This final rule is technical in nature. It involves transferring data reporting requirements under 45 CFR part 61 for the Healthcare Integrity and Protection Data Bank (HIPDB) to 45 CFR part 60 for the National Practitioner Data Bank (NPDB), another data bank receiving like reports. The result of this transfer does not increase the regulatory burden on affected entities; it alleviates duplication.

1. Executive Orders 12866 and 13563

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule is not being treated as a ''significant regulatory action'' under section 3(f) of Executive Order 12866. Accordingly, the rule has not been reviewed by the Office of Management and Budget.

2. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) and the Small Business Regulatory Enforcement and Fairness Act of 1996, which amended the RFA, require HRSA to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Further, in accordance with the RFA, if a rule has a significant economic effect on a substantial number of small entities, the Secretary must specifically consider the economic effect of the rule on small

entities and analyze regulatory options that could lessen the impact of the rule. The purpose of the final rule is to eliminate duplication between the HIPDB and the NPDB. The NPDB will serve as the sole repository for all information previously captured in the HIPDB. This will not substantially alter reporting requirements. Therefore, the Secretary certifies that these regulations will not have a significant impact on a substantial number of small entities.

3. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4) requires agencies to assess anticipated costs and benefits for any rulemaking that may result in an annual expenditure of $139 million or more by state, local, or tribal governments, or the private sector. HRSA has determined that this rule does not impose any additional mandates on state, local, or tribal governments, or the private sector, that will result in an annual expenditure of $139 million or more. A full analysis under the UMRA is not necessary.

4. Executive Order 13132—Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule imposing substantial direct requirements or costs on state and local governments, preempts state law, or otherwise has federalism implications. In reviewing this rule under the threshold criteria of Executive Order 13132, the Secretary has determined that this rule will not significantly affect the rights, roles, and responsibilities of state or local governments because the actions that are already reported under HIPDB are merely shifting to the NPDB.

B. Paperwork Reduction Act

This final rule does not add any new reporter categories, but information-collection requirements may be expanded for some reporters. For instance, the final rule interprets statutory references to ''entity'' reporting subjects under the amended section 1921 to include ''health care providers and suppliers.'' As a result, accreditation entities will now be required to report actions taken against providers and suppliers in addition to those subjects that meet the definition of a ''health care entity.'' However, these sorts of expansions are subtle and will not significantly alter the current requirements under the HIPDB and NPDB regulations. The NPDB and HIPDB regulations contain information collection requirements that have been approved by OMB under the Paperwork Reduction Act of 1995 (PRA) and assigned control numbers 0915–0126 and 0915–0239, respectively.

The only impact of the merging of 45 CFR part 61 with 45 CFR part 60 is to eliminate duplication and streamline internal operations. By combining two data banks into a single data bank, the need to capture like information in two data bases is eliminated.

Dated: March 20, 2013.

Mary Wakefield,

Administrator, Health Resources and Services Administration.

Approved: March 26, 2013.

Kathleen Sebelius,

Secretary.

List of Subjects

45 CFR Part 60

Billing and transportation services, Claims, Durable medical equipment suppliers and manufacturers, Fraud, Health care insurers, Health maintenance organizations (HMOs), Health professions, Hospitals, Home health care agencies, Hospitals, Insurance companies, Malpractice, Pharmaceutical suppliers and manufacturers, Reporting and recordkeeping requirements, Skilled nursing facilities.

45 CFR Part 61

Confidential business information, Health care, Health professions, Penalties, Reporting and recordkeeping requirements

For the reasons set forth in the preamble, HHS amends 45 CFR subtitle A as follows:

■ 1. Part 60 is revised to read as follows:

PART 60—NATIONAL PRACTITIONER DATA BANK

Subpart A—General Provisions

Sec.
60.1 The National Practitioner Data Bank.
60.2 Applicability.
60.3 Definitions.

Subpart B—Reporting of Information

Sec.
60.4 How information must be reported.
60.5 When information must be reported.
60.6 Reporting errors, omissions, revisions or whether an action is on appeal.
60.7 Reporting medical malpractice payments.
60.8 Reporting licensure actions taken by Boards of Medical Examiners.
60.9 Reporting licensure and certification actions taken by states.
60.10 Reporting Federal licensure and certification actions.
60.11 Reporting negative actions or findings taken by peer review organizations or private accreditation entities.
60.12 Reporting adverse actions taken against clinical privileges.
60.13 Reporting Federal or state criminal convictions related to the delivery of a health care item or service.
60.14 Reporting civil judgments related to the delivery of a health care item or service.
60.15 Reporting exclusions from participation in government health care programs.
60.16 Reporting other adjudicated actions or decisions.

Subpart C—Disclosure of Information by the National Practitioner Data Bank

Sec.
60.17 Information which hospitals must request from the National Practitioner Data Bank.
60.18 Requesting information from the National Practitioner Data Bank.
60.19 Fees applicable to requests for information.
60.20 Confidentiality of National Practitioner Data Bank information.
60.21 How to dispute the accuracy of National Practitioner Data Bank information.
60.22 Immunity.

Authority: 42 U.S.C. 11101–11152; 42 U.S.C. 1396r–2; 42 U.S.C. 1320a–7e

Subpart A—General Provisions

§ 60.1 The National Practitioner Data Bank.

The Health Care Quality Improvement Act of 1986 (HCQIA), as amended, title IV of Public Law 99–660 (42 U.S.C. 11101 et seq.) (hereinafter referred to as ''title IV''), authorizes the Secretary to establish (either directly or by contract) a National Practitioner Data Bank (NPDB) to collect and release certain information relating to the professional competence and conduct of physicians, dentists and other health care practitioners. Section 1921 of the Social Security Act (hereinafter referred to as ''section 1921''), as amended, (42 U.S.C. 1396r–2) expanded the requirements under the NPDB and requires each state to adopt a system of reporting to the Secretary adverse licensure or certification actions taken against health care practitioners, health care entities, providers, and suppliers, as well as certain final adverse actions taken by state law and fraud enforcement agencies against health care practitioners, providers, and suppliers. Section 1128E of the Social Security Act (hereinafter referred to as ''section 1128E''), as amended, (42 U.S.C. 1320a–7e) authorizes the Secretary to implement a national healthcare fraud and abuse data collection program for the reporting and disclosing of certain final adverse actions taken by Federal Government agencies and health plans against health care practitioners, providers, and suppliers. Information from section 1921 and section 1128E is to be reported and distributed through

the NPDB. The regulations in this part set forth the reporting and disclosure requirements for the NPDB, as well as procedures to dispute the accuracy of information contained in the NPDB.

§ 60.2 Applicability.

The regulations in this part establish reporting requirements applicable to hospitals, health care entities, Boards of Medical Examiners, professional societies of health care practitioners which take adverse licensure or professional review actions; state licensing or certification authorities, peer review organizations, and private accreditation entities that take licensure or certification actions or negative actions or findings against health care practitioners, health care entities, providers, or suppliers; entities (including insurance companies) making payments as a result of medical malpractice actions or claims; Federal Government agencies, state law and fraud enforcement agencies and health plans that take final adverse actions against health care practitioners, providers, and suppliers. They also establish procedures to enable individuals or entities to obtain information from the NPDB or to dispute the accuracy of NPDB information.

§ 60.3 Definitions.

Adversely affecting means reducing, restricting, suspending, revoking, or denying clinical privileges or membership in a health care entity.

Affiliated or associated refers to health care entities with which a subject of a final adverse action has a business or professional relationship. This includes, but is not limited to, organizations, associations, corporations, or partnerships. This also includes a professional corporation or other business entity composed of a single individual.

Board of Medical Examiners, or Board, means a body or subdivision of such body which is designated by a state for the purpose of licensing, monitoring, and disciplining physicians or dentists. This term includes a Board of Osteopathic Examiners or its subdivision, a Board of Dentistry or its subdivision, or an equivalent body as determined by the state. Where the Secretary, pursuant to section 423(c)(2) of the HCQIA (42 U.S.C. 11112(c)), has designated an alternate entity to carry out the reporting activities of § 60.12 of this part due to a Board's failure to comply with § 60.8 of this part, the term Board of Medical Examiners or Board refers to this alternate entity.

Civil judgment means a court-ordered action rendered in a Federal or state court proceeding, other than a criminal proceeding. This reporting requirement does not include Consent Judgments that have been agreed upon and entered to provide security for civil settlements in which there was no finding or admission of liability.

Clinical privileges means the authorization by a health care entity to a health care practitioner for the provision of health care services, including privileges and membership on the medical staff.

Criminal conviction means a conviction as described in section 1128(i) of the Social Security Act.

Dentist means a doctor of dental surgery, doctor of dental medicine, or the equivalent who is legally authorized to practice dentistry by a state (or who, without authority, holds himself or herself out to be so authorized).

Exclusion means a temporary or permanent debarment of an individual or entity from participation in any government health-related program, in accordance with which items or services furnished by such person or entity will not be reimbursed under any government health-related program.

Federal Government agency includes, but is not limited to:

(1) The U.S. Department of Justice;

(2) The U.S. Department of Health and Human Services;

(3) Federal law enforcement agencies, including law enforcement investigators;

(4) Any other Federal agency that either administers or provides payment for the delivery of health care services, including, but not limited to the U.S. Department of Defense and the U.S. Department of Veterans Affairs; and

(5) Federal agencies responsible for the licensing and certification of health care practitioners, providers, and suppliers.

Formal peer review process means the conduct of professional review activities through formally adopted written procedures which provide for adequate notice and an opportunity for a hearing.

Formal proceeding means a proceeding held before a state licensing or certification authority, peer review organization, or private accreditation entity that maintains defined rules, policies, or procedures for such a proceeding.

Health care entity means, for purposes of this part:

(1) A hospital;

(2) An entity that provides health care services, and engages in professional review activity through a formal peer review process for the purpose of furthering quality health care, or a committee of that entity; or

(3) A professional society or a committee or agent thereof, including those at the national, state, or local level, of health care practitioners that engages in professional review activity through a formal peer review process, for the purpose of furthering quality health care.

(4) For purposes of paragraph (2) of this definition, an entity includes: a health maintenance organization which is licensed by a state or determined to be qualified as such by the Department of Health and Human Services; and any group or prepaid medical or dental practice which meets the criteria of paragraph (2).

Health care practitioner, licensed health care practitioner, licensed practitioner, or practitioner means an individual who is licensed or otherwise authorized by a state to provide health care services (or any individual who, without authority, holds himself or herself out to be so licensed or authorized).

Health care provider means, for purposes of this part, a provider of services as defined in section 1861(u) of the Social Security Act; any organization (including a health maintenance organization, preferred provider organization or group medical practice) that provides health care services and follows a formal peer review process for the purpose of furthering quality health care, and any other organization that, directly or through contracts, provides health care services.

Health care supplier means, for purposes of this part, a provider of medical and other health care services as described in section 1861(s) of the Social Security Act; or any individual or entity, other than a provider, who furnishes, whether directly or indirectly, or provides access to, health care services, supplies, items, or ancillary services (including, but not limited to, durable medical equipment suppliers, manufacturers of health care items, pharmaceutical suppliers and manufacturers, health record services [such as medical, dental, and patient records], health data suppliers, and billing and transportation service suppliers). The term also includes any individual or entity under contract to provide such supplies, items, or ancillary services; health plans as defined in this section (including employers that are self-insured); and health insurance producers (including but not limited to agents, brokers, solicitors, consultants, and reinsurance intermediaries).

Health plan means, for purposes of this part, a plan, program or organization that provides health benefits, whether directly, through insurance, reimbursement or otherwise, and includes but is not limited to:

(1) A policy of health insurance;

(2) A contract of a service benefit organization;

(3) A membership agreement with a health maintenance organization or other prepaid health plan;

(4) A plan, program, agreement, or other mechanism established, maintained, or made available by a self-insured employer or group of self-insured employers, a health care practitioner, provider, or supplier group, third-party administrator, integrated health care delivery system, employee welfare association, public service group or organization or professional association;

(5) An insurance company, insurance service or insurance organization that is licensed to engage in the business of selling health care insurance in a state and which is subject to state law which regulates health insurance; and

(6) An organization that provides benefit plans whose coverage is limited to outpatient prescription drugs.

Hospital means, for purposes of this part, an entity described in paragraphs (1) and (7) of section 1861(e) of the Social Security Act.

Medical malpractice action or claim means a written complaint or claim demanding payment based on a health care practitioner's provision of or failure to provide health care services, and includes the filing of a cause of action based on the law of tort, brought in any state or Federal court or other adjudicative body.

Negative action or finding by a Federal or State licensing or certification authority, peer review organization, or private accreditation entity means:

(1) A final determination of denial or termination of an accreditation status from a private accreditation entity that indicates a risk to the safety of a patient(s) or quality of health care services;

(2) Any recommendation by a peer review organization to sanction a health care practitioner; or

(3) Any negative action or finding that, under the state's law, is publicly available information and is rendered by a licensing or certification authority, including but not limited to, limitations on the scope of practice, liquidations, injunctions, and forfeitures. This definition also includes final adverse actions rendered by a Federal or state licensing or certification authority, such as exclusions, revocations, or suspension of license or certification, that occur in conjunction with settlements in which no finding of liability has been made (although such a settlement itself is not reportable under the statute). This definition excludes administrative fines or citations and corrective action plans and other personnel actions, unless they are:

(i) Connected to the delivery of health care services, or

(ii) Taken in conjunction with other adverse licensure or certification actions such as revocation, suspension, censure, reprimand, probation, or surrender.

Organization name means the subject's business or employer at the time the underlying acts occurred. If more than one business or employer is applicable, the one most closely related to the underlying acts should be reported as the ''organization name,'' with the others being reported as ''affiliated or associated health care entities.''

Organization type means a description of the nature of that business or employer.

Other adjudicated actions or decisions means formal or official final actions taken against a health care practitioner, provider, or supplier by a Federal governmental agency, a state law or fraud enforcement agency, or a health plan, which include the availability of a due process mechanism, and are based on acts or omissions that affect or could affect the payment, provision, or delivery of a health care item or service. For example, a formal or official final action taken by a Federal governmental agency, a state law or fraud enforcement agency, or a health plan may include, but is not limited to, a personnel-related action such as suspensions without pay, reductions in pay, reductions in grade for cause, terminations, or other comparable actions. A hallmark of any valid adjudicated action or decision is the availability of a due process mechanism. The fact that the subject elects not to use the due process mechanism provided by the authority bringing the action is immaterial, as long as such a process is available to the subject before the adjudicated action or decision is made final. In general, if an ''adjudicated action or decision'' follows an agency's established administrative procedures (which ensure that due process is available to the subject of the final adverse action), it would qualify as a reportable action under this definition. This definition specifically excludes clinical privileging actions taken by Federal Government agencies or state law and fraud enforcement agencies and similar paneling decisions made by health plans. This definition does not include overpayment determinations made by Federal or state government programs, their contractors or health plans, and it does not include denial of claims determinations made by Federal Government agencies, state law or fraud enforcement agencies, or health plans. This definition also does not include business or administrative decisions taken by health plans that result in contract terminations unrelated to health care fraud or abuse or quality of care (e.g., when a practitioner's contract is terminated because the practitioner no longer practices at a facility in the health plan's network, or a health plan terminates all provider contracts in a certain geographic area because it ceases business operations in that area). For health plans that are not government entities, an action taken following adequate notice and the opportunity for a hearing that meets the standards of due process set out in section 412(b) of the HCQIA (42 U.S.C. 11112(b)) also would qualify as a reportable action under this definition.

Peer review organization means, for purposes of this part, an organization with the primary purpose of evaluating the quality of patient care practices or services ordered or performed by health care practitioners measured against objective criteria which define acceptable and adequate practice through an evaluation by a sufficient number of health care practitioners in such an area to ensure adequate peer review. The organization has due process mechanisms available to health care practitioners. This definition excludes utilization and quality control peer review organizations described in Part B of Title XI of the Social Security Act (referred to as QIOs) and other organizations funded by the Centers for Medicare & Medicaid Services (CMS) to support the QIO program.

Physician means, for purposes of this part, a doctor of medicine or osteopathy legally authorized to practice medicine or surgery by a state (or who, without authority, holds himself or herself out to be so authorized).

Private accreditation entity means an entity or organization that:

(1) Evaluates and seeks to improve the quality of health care provided by a health care entity, provider, or supplier;

(2) Measures a health care entity's, provider's, or supplier's performance based on a set of standards and assigns a level of accreditation;

(3) Conducts ongoing assessments and periodic reviews of the quality of health care provided by a health care entity, provider, or supplier; and

(4) Has due process mechanisms available to health care entities, providers, or suppliers.

Professional review action means an action or recommendation of a health care entity:

(1) Taken in the course of professional review activity;

(2) Based on the professional competence or professional conduct of an individual health care practitioner which affects or could affect adversely the health or welfare of a patient or patients; and

(3) Which adversely affects or may adversely affect the clinical privileges or membership in a professional society of the health care practitioner.

(4) This term excludes actions which are primarily based on:

(i) The health care practitioner's association, or lack of association, with a professional society or association;

(ii) The health care practitioner's fees or the health care practitioner's advertising or engaging in other competitive acts intended to solicit or retain business;

(iii) The health care practitioner's participation in prepaid group health plans, salaried employment, or any other manner of delivering health services whether on a fee-for-service or other basis;

(iv) A health care practitioner's association with, supervision of, delegation of authority to, support for, training of, or participation in a private group practice with, a member or members of a particular class of health care practitioner or professional; or

(v) Any other matter that does not relate to the competence or professional conduct of a health care practitioner.

Professional review activity means an activity of a health care entity with respect to an individual health care practitioner:

(1) To determine whether the health care practitioner may have clinical privileges with respect to, or membership in, the entity;

(2) To determine the scope or conditions of such privileges or membership; or

(3) To change or modify such privileges or membership.

Quality Improvement Organization means a utilization and quality control peer review organization (as defined in part B of title XI of the Social Security Act) that:

(1)(i) Is composed of a substantial number of the licensed doctors of medicine and osteopathy engaged in the practice of medicine or surgery in the area and who are representative of the practicing physicians in the area, designated by the Secretary under section 1153, with respect to which the entity shall perform services under this part, or

(ii) Has available to it, by arrangement or otherwise, the services of a sufficient number of licensed doctors of medicine or osteopathy engaged in the practice of medicine or surgery in such area to assure that adequate peer review of the services provided by the various medical specialties and subspecialties can be assured;

(2) Is able, in the judgment of the Secretary, to perform review functions required under section 1154 in a manner consistent with the efficient and effective administration of this part and to perform reviews of the pattern of quality of care in an area of medical practice where actual performance is measured against objective criteria which define acceptable and adequate practice; and

(3) Has at least one individual who is a representative of consumers on its governing body.

Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

State means the fifty states, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

State law or fraud enforcement agency includes, but is not limited to:

(1) A state law enforcement agency;

(2) A state Medicaid fraud control unit (as defined in section 1903(q) of the Social Security Act); and

(3) A state agency administering (including those providing payment for services) or supervising the administration of a government health care program (as defined in section 1128(h) of the Social Security Act).

State licensing or certification agency includes, but is not limited to, any authority of a state (or of a political subdivision thereof) responsible for the licensing or certification of health care practitioners (or any peer review organization or private accreditation entity reviewing the services provided by health care practitioners), health care entities, providers, or suppliers. Examples of such state agencies include Departments of Professional Regulation, Health, Social Services (including State Survey and Certification and Medicaid Single State agencies), Commerce, and Insurance.

Voluntary surrender of license or certification means a surrender made after a notification of investigation or a formal official request by a Federal or state licensing or certification authority for a health care practitioner, health care entity, provider, or supplier to surrender the license or certification (including certification agreements or contracts for participation in government health care programs). The definition also includes those instances where a health care practitioner, health care entity, provider, or supplier voluntarily surrenders a license or certification (including program participation agreements or contracts) in exchange for a decision by the licensing or certification authority to cease an investigation or similar proceeding, or in return for not conducting an investigation or proceeding, or in lieu of a disciplinary action.

Subpart B—Reporting of Information

§ 60.4 How information must be reported.

Information must be reported to the NPDB as required under §§ 60.7, 60.8, 60.9, 60.10, 60.11, 60.12, 60.13, 60.14, 60.15 and 60.16 in such form and manner as the Secretary may prescribe.

§ 60.5 When information must be reported.

Information required under §§ 60.7, 60.8, and 60.12 must be submitted to the NPDB within 30 days following the action to be reported, beginning with actions occurring on or after September 1, 1990; information required under § 60.11 must be submitted to the NPDB within 30 days following the action to be reported, beginning with actions occurring on or after January 1, 1992; and information required under §§ 60.9, 60.10, 60.13, 60.14, 60.15, and 60.16 must be submitted to the NPDB within 30 days following the action to be reported, beginning with actions occurring on or after August 21, 1996. Persons or entities responsible for submitting reports of malpractice payments (§ 60.7), negative actions or findings (§ 60.11), or adverse actions (§ 60.12) must additionally provide to their respective state authorities a copy of the report they submit to the NPDB. Following is the list of reportable actions:

(a) Malpractice payments (§ 60.7);

(b) Licensure and certification actions (§§ 60.8, 60.9, and 60.10);

(c) Negative actions or findings (§ 60.11);

(d) Adverse actions (§ 60.12);

(e) Health Care-related Criminal Convictions (§ 60.13);

(f) Health Care-related Civil Judgments (§ 60.14);

(g) Exclusions from government health care programs (§ 60.15); and

(h) Other adjudicated actions of decisions (§ 60.16).

§ 60.6 Reporting errors, omissions, revisions or whether an action is on appeal.

(a) Persons and entities are responsible for the accuracy of information which they report to the NPDB. If errors or omissions are found after information has been reported, the person or entity which reported it must send an addition or correction to the NPDB and in the case of reports made under § 60.12 of this part, also to the Board of Medical Examiners, as soon as possible. The NPDB will not accept requests for readjudication of the case by the NPDB, and will not examine the underlying merits of a reportable action.

(b) An individual or entity which reports information on licensure or certification, negative actions or findings, clinical privileges, criminal convictions, civil or administrative judgments, exclusions, or adjudicated actions or decisions under §§ 60.8, 60.9, 60.10, 60.11, 60.12, 60.13, 60.14, 60.15, or 60.16 must also report any revision of the action originally reported. Revisions include, but are not limited to, reversal of a professional review action or reinstatement of a license. In the case of actions reported under §§ 60.9, 60.10, 60.13, 60.14, 60.15 or 60.16, revisions also include whether an action is on appeal. Revisions are subject to the same time constraints and procedures of §§ 60.5, 60.8, 60.9, 60.10, 60.11, 60.12, 60.13, 60.14, 60.15, or 60.16 as applicable to the original action which was reported.

(c) The subject will be sent a copy of all reports, including revisions and corrections to the report.

(d) Upon receipt of a report, the subject:

(1) Can accept the report as written;

(2) May provide a statement to the NPDB that will be permanently appended to the report, either directly or through a designated representative; (The NPDB will distribute the statement to queriers, where identifiable, and to the reporting entity and the subject of the report. Only the subject can, upon request, make changes to the statement. The NPDB will not edit the statement; however the NPDB reserves the right to redact personal identifying and offensive language that does not change the factual nature of the statement.) or

(3) May follow the dispute process in accordance with § 60.21.

§ 60.7 Reporting medical malpractice payments.

(a) *Who must report.* Each entity, including an insurance company, which makes a payment under an insurance policy, self-insurance, or otherwise, for the benefit of a health care practitioner in settlement of or in satisfaction in whole or in part of a claim or a judgment against such health care practitioner for medical malpractice, must report information as set forth in paragraph (b) of this section to the NPDB and to the appropriate state licensing board(s) in the state in which the act or omission upon which the medical malpractice claim was based. For purposes of this section, the waiver of an outstanding debt is not construed as a ''payment'' and is not required to be reported.

(b) *What information must be reported.* Entities described in paragraph (a) of this section must report the following information:

(1) With respect to the health care practitioner for whose benefit the payment is made:

(i) Name,

(ii) Work address,

(iii) Home address, if known,

(iv) Social Security Number, if known, and if obtained in accordance with section 7 of the Privacy Act of 1974 (5 U.S.C. 552a note),

(v) Date of birth,

(vi) Name of each professional school attended and year of graduation,

(vii) For each professional license: the license number, the field of licensure, and the name of the state or territory in which the license is held,

(viii) Drug Enforcement Administration registration number, if known,

(ix) Name of each hospital with which he or she is affiliated, if known;

(2) With respect to the reporting entity:

(i) Name and address of the entity making the payment,

(ii) Name, title, and telephone number of the responsible official submitting the report on behalf of the entity, and

(iii) Relationship of the reporting entity to the health care practitioner for whose benefit the payment is made;

(3) With respect to the judgment or settlement resulting in the payment:

(i) Where an action or claim has been filed with an adjudicative body, identification of the adjudicative body and the case number,

(ii) Date or dates on which the act(s) or omission(s) which gave rise to the action or claim occurred,

(iii) Date of judgment or settlement,

(iv) Amount paid, date of payment, and whether payment is for a judgment or a settlement,

(v) Description and amount of judgment or settlement and any conditions attached thereto, including terms of payment,

(vi) A description of the acts or omissions and injuries or illnesses upon which the action or claim was based,

(vii) Classification of the acts or omissions in accordance with a reporting code adopted by the Secretary, and

(viii) Other information as required by the Secretary from time to time after publication in the **Federal Register** and after an opportunity for public comment.

(c) *Sanctions.* Any entity that fails to report information on a payment required to be reported under this section is subject to a civil money penalty not to exceed the amount specified at 42 CFR 1003.103(c).

(d) *Interpretation of information.* A payment in settlement of a medical malpractice action or claim shall not be construed as creating a presumption that medical malpractice has occurred.

§ 60.8 Reporting licensure actions taken by Boards of Medical Examiners.

(a) *What actions must be reported.* Each Board of Medical Examiners must report to the NPDB any action based on reasons relating to a physician's or dentist's professional competence or professional conduct:

(1) Which revokes or suspends (or otherwise restricts) a physician's or dentist's license,

(2) Which censures, reprimands, or places on probation a physician or dentist, or

(3) Under which a physician's or dentist's license is surrendered.

(b) *Information that must be reported.* The Board must report the following information for each action:

(1) The physician's or dentist's name,

(2) The physician's or dentist's work address,

(3) The physician's or dentist's home address, if known,

(4) The physician's or dentist's Social Security number or Individual Tax Identification Number (ITIN), if known, and if obtained in accordance with section 7 of the Privacy Act of 1974 (5 U.S.C. 552a note),

(5) National Provider Identifier (NPI),

(6) The physician's or dentist's date of birth,

(7) Name of each professional school attended by the physician or dentist and year of graduation,

(8) For each professional license, the physician's or dentist's license number, the field of licensure and the name of the state or territory in which the license is held,

(9) The physician's or dentist's Drug Enforcement Administration registration number, if known,

(10) A description of the acts or omissions or other reasons for the action taken,

(11) A description of the Board action, the date the action was taken, its effective date and duration,

(12) Classification of the action in accordance with a reporting code adopted by the Secretary, and

(13) Other information as required by the Secretary from time to time after publication in the **Federal Register** and after an opportunity for public comment.

(c) *Sanctions.* If, after notice of noncompliance and providing opportunity to correct noncompliance, the Secretary determines that a Board has failed to submit a report as required by this section, the Secretary will designate another qualified entity for the reporting of information under § 60.12 of this part.

§ 60.9 Reporting licensure and certification actions taken by states.

(a) *What actions must be reported.* Each state is required to adopt a system of reporting to the NPDB actions, as listed below, which are taken against a health care practitioner, health care entity, provider, or supplier (all as defined in § 60.3 of this part). The actions taken must be as a result of formal proceedings (as defined in § 60.3). The actions which must be reported are:

(1) Any adverse action taken by the licensing or certification authority of the state as a result of a formal proceeding, including revocation or suspension of a license, or certification agreement or contract for participation in a government health care program (and the length of any such suspension), reprimand, censure, or probation;

(2) Any dismissal or closure of the formal proceeding by reason of the health care practitioner, health care entity, provider, or supplier surrendering the license or certification agreement or contract for participation in a government health care program, or leaving the state or jurisdiction;

(3) Any other loss of license or loss of the certification agreement or contract for participation in a government health care program, or the right to apply for, or renew, a license or certification agreement or contract of the health care practitioner, health care entity, provider or supplier, whether by operation of law, voluntary surrender, nonrenewal (excluding non-renewals due to nonpayment of fees, retirement, or change to inactive status), or otherwise;

(4) Any negative action or finding by such authority, organization, or entity regarding the health care practitioner, health care entity, provider, or supplier.

(b) *What information must be reported.* Each state must report the following information (not otherwise reported under § 60.8 of this part):

(1) If the subject is an individual, personal identifiers, including:

(i) Name,

(ii) Social Security Number or ITIN, if known, and if obtained in accordance with section 7 of the Privacy Act of 1974 (5 U.S.C. 552a note),

(iii) Home address or address of record,

(iv) Sex, and

(v) Date of birth.

(2) If the subject is an individual, employment or professional identifiers, including:

(i) Organization name and type,

(ii) Occupation and specialty, if applicable,

(iii) National Provider Identifier (NPI),

(iv) Name of each professional school attended and year of graduation, and

(v) With respect to the professional license (including professional certification and registration) on which the reported action was taken, the license number, the field of licensure, and the name of the state or territory in which the license is held.

(3) If the subject is an organization, identifiers, including:

(i) Name,

(ii) Business address,

(iii) Federal Employer Identification Number (FEIN), or Social Security Number when used by the subject as a Taxpayer Identification Number (TIN),

(iv) The NPI,

(v) Type of organization, and

(vi) With respect to the license (including certification and registration) on which the reported action was taken, the license and the name of the state or territory in which the license is held.

(4) For all subjects:

(i) A narrative description of the acts or omissions and injuries upon which the reported action was based,

(ii) Classification of the acts or omissions in accordance with a reporting code adopted by the Secretary,

(iii) Classification of the action taken in accordance with a reporting code adopted by the Secretary, and the amount of any monetary penalty resulting from the reported action,

(iv) The date the action was taken, its effective date and duration,

(v) Name of the agency taking the action,

(vi) Name and address of the reporting entity, and

(vii) The name, title and telephone number of the responsible official submitting the report on behalf of the reporting entity.

(c) *What information may be reported, if known.* Reporting entities described in paragraph (a) of this section may voluntarily report, if known, the following information:

(1) If the subject is an individual, personal identifiers, including:

(i) Other name(s) used,

(ii) Other address,

(iii) FEIN, when used by the individual as a TIN, and

(iv) If deceased, date of death.

(2) If the subject is an individual, employment or professional identifiers, including:

(i) Other state professional license number(s), field(s) of licensure, and the name(s) of the state or territory in which the license is held,

(ii) Other numbers assigned by Federal or state agencies, including, but not limited to DEA registration number(s), Unique Physician Identification Number(s) (UPIN), and Medicaid and Medicare provider number(s),

(iii) Name(s) and address(es) of any health care entity with which the subject is affiliated or associated, and

(iv) Nature of the subject's relationship to each associated or affiliated health care entity.

(3) If the subject is an organization, identifiers, including:

(i) Other name(s) used,

(ii) Other address(es) used,

(iii) Other FEIN(s) or Social Security Number(s) used,

(iv) Other NPI(s) used,

(v) Other state license number(s) and the name(s) of the state or territory in which the license is held,

(vi) Other numbers assigned by Federal or state agencies, including, but not limited to DEA registration number(s), Clinical Laboratory Improvement Act (CLIA) number(s), Food and Drug Administration (FDA) number(s), and Medicaid and Medicare provider number(s),

(vii) Names and titles of principal officers and owners,

(viii) Name(s) and address(es) of any health care entity with which the subject is affiliated or associated, and

(ix) Nature of the subject's relationship to each associated or affiliated health care entity.

(4) For all subjects:

(i) Whether the subject will be automatically reinstated.

(ii) The date of appeal, if any.

(d) *Access to documents.* Each state must provide the Secretary (or an entity designated by the Secretary) with access to the documents underlying the actions described in paragraphs (a)(1) through (4) of this section, as may be necessary for the Secretary to determine the facts and circumstances concerning the actions and determinations for the purpose of carrying out section 1921.

(e) Sanctions for failure to report. The Secretary will provide for a publication of a public report that identifies failures to report information on adverse actions as required to be reported under this section.

§ 60.10 Reporting Federal licensure and certification actions.

(a) *What actions must be reported.* Federal licensing and certification agencies must report to the NPDB the following final adverse actions that are taken against a health care practitioner, physician, dentist, provider, or supplier (regardless of whether the final adverse action is the subject of a pending appeal):

(1) Formal or official actions, such as revocation or suspension of a license or certification agreement or contract for participation in government health care programs (and the length of any such suspension), reprimand, censure or probation,

(2) Any dismissal or closure of the proceedings by reason of the health care practitioner, provider, or supplier surrendering their license or certification agreement or contract for participation in government health care programs, or leaving the state or jurisdiction,

(3) Any other loss of the license or loss of the certification agreement or contract for participation in government health care programs, or the right to apply for, or renew, a license or certification agreement or contract of the health care practitioner, provider, or supplier, whether by operation of law, voluntary surrender, nonrenewal (excluding non-renewals due to nonpayment of fees, retirement, or change to inactive status), or otherwise, and

(4) Any other negative action or finding by such Federal agency that is publicly available information.

(b) *What information must be reported.* Each Federal agency described in paragraph (a) of this section must report the following information:

(1) If the subject is an individual, personal identifiers, including:

(i) Name,

(ii) Social Security Number or ITIN,

(iii) Home address or address of record,

(iv) Sex, and

(v) Date of birth.

(2) If the subject is an individual, employment or professional identifiers, including:

(i) Organization name and type,

(ii) Occupation and specialty, if applicable,

(iii) National Provider Identifier (NPI),

(iv) Name of each professional school attended and year of graduation, and

(v) With respect to the state professional license (including professional certification and registration) on which the reported action was taken, the license number, the field of licensure, and the name of the state or territory in which the license is held.

(3) If the subject is an organization, identifiers, including:

(i) Name,

(ii) Business address,

(iii) Federal Employer Identification Number (FEIN), or Social Security Number (or ITIN) when used by the subject as a Taxpayer Identification Number (TIN),

(iv) The NPI,

(v) Type of organization, and

(vi) With respect to the state license (including certification and registration) on which the reported action was taken, the license and the name of the state or territory in which the license is held.

(4) For all subjects:

(i) A narrative description of the acts or omissions and injuries upon which the reported action was based,

(ii) Classification of the acts or omissions in accordance with a reporting code adopted by the Secretary,

(iii) Classification of the action taken in accordance with a reporting code adopted by the Secretary, and the amount of any monetary penalty resulting from the reported action,

(iv) The date the action was taken, its effective date and duration,

(v) Name of the agency taking the action,

(vi) Name and address of the reporting entity, and

(vii) The name, title, and telephone number of the responsible official submitting the report on behalf of the reporting entity.

(c) *What information may be reported, if known.* Reporting entities described in paragraph (a) of this section may voluntarily report, if known, the following information:

(1) If the subject is an individual, personal identifiers, including:

(i) Other name(s) used,

(ii) Other address,

(iii) FEIN, when used by the individual as a TIN, and

(iv) If deceased, date of death.

(2) If the subject is an individual, employment or professional identifiers, including:

(i) Other state professional license number(s), field(s) of licensure, and the name(s) of the state or territory in which the license is held,

(ii) Other numbers assigned by Federal or state agencies, including, but not limited to DEA registration number(s), Unique Physician Identification Number(s) (UPIN), and Medicaid and Medicare provider number(s),

(iii) Name(s) and address(es) of any health care entity with which the subject is affiliated or associated, and

(iv) Nature of the subject's relationship to each associated or affiliated health care entity.

(3) If the subject is an organization, identifiers, including:

(i) Other name(s) used,

(ii) Other address(es) used,

(iii) Other FEIN(s) or Social Security Number(s) used,

(iv) Other NPI(s) used,

(v) Other state license number(s) and the name(s) of the state or territory in which the license is held,

(vi) Other numbers assigned by Federal or state agencies, including, but not limited to DEA registration number(s), Clinical Laboratory Improvement Act (CLIA) number(s), Food and Drug Administration (FDA) number(s), and Medicaid and Medicare provider number(s),

(vii) Names and titles of principal officers and owners,

(viii) Name(s) and address(es) of any health care entity with which the subject is affiliated or associated, and

(ix) Nature of the subject's relationship to each associated or affiliated health care entity.

(4) For all subjects:

(i) Whether the subject will be automatically reinstated.

(ii) The date of appeal, if any.

(d) Sanctions for failure to report. The Secretary will provide for a publication of a public report that identifies those agencies that have failed to report information on adverse actions as required to be reported under this section.

§ 60.11 Reporting negative actions or findings taken by peer review organizations or private accreditation entities.

(a) *What actions must be reported.* Peer review organizations and private accreditation entities are required to report any negative actions or findings (as defined in § 60.3 of this part) which are taken against a health care practitioner, health care entity, provider, or supplier to the NPDB and provide a copy to the appropriate state licensing or certification agency. The health care practitioner, health care entity, provider, or supplier must be licensed or otherwise authorized by the state to provide health care services. The actions taken must be as a result of formal proceedings (as defined in § 60.3).

(b) *What information must be reported.* Each peer review organization

and private accreditation entity must report the information as required in § 60.9(b) of this part.

(c) *What information may be reported, if known.* Each peer review organization and private accreditation entity should report, if known, the information as described in § 60.9(c).

(d) *Access to documents.* Each peer review organization and private accreditation entity must provide the Secretary (or an entity designated by the Secretary) with access to the documents underlying the actions described in this section as may be necessary for the Secretary to determine the facts and circumstances concerning the actions and determinations for the purpose of carrying out section 1921.

§ 60.12 Reporting adverse actions taken against clinical privileges.

(a) *Reporting by health care entities to the NPDB.* (1) *Actions that must be reported and to whom the report must be made.* Each health care entity must report to the NPDB and provide a copy of the report to the Board of Medical Examiners in the state in which the health care entity is located the following actions:

(i) Any professional review action that adversely affects the clinical privileges of a physician or dentist for a period longer than 30 days,

(ii) Acceptance of the surrender of clinical privileges or any restriction of such privileges by a physician or dentist:

(A) While the physician or dentist is under investigation by the health care entity relating to possible incompetence or improper professional conduct, or

(B) In return for not conducting such an investigation or proceeding, or

(iii) In the case of a health care entity which is a professional society, when it takes a professional review action concerning a physician or dentist.

(2) *Voluntary reporting on other health care practitioners.* A health care entity may report to the NPDB information as described in paragraph (a)(3) of this section concerning actions described in paragraph (a)(1) in this section with respect to other health care practitioners.

(3) *What information must be reported.* The health care entity must report the following information concerning actions described in paragraph (a)(1) of this section with respect to a physician or dentist:

(i) Name,

(ii) Work address,

(iii) Home address, if known,

(iv) Social Security Number, if known, and if obtained in accordance with section 7 of the Privacy Act of 1974,

(v) Date of birth,

(vi) Name of each professional school attended and year of graduation,

(vii) For each professional license: the license number, the field of licensure, and the name of the state or territory in which the license is held,

(viii) DEA registration number, if known,

(ix) A description of the acts or omissions or other reasons for privilege loss, or, if known, for surrender,

(x) Action taken, date the action was taken, and effective date of the action, and

(xi) Other information as required by the Secretary from time to time after publication in the **Federal Register** and after an opportunity for public comment.

(b) *Reporting by the Board of Medical Examiners to the NPDB.* Each Board must report any known instances of a health care entity's failure to report information as required under paragraph (a)(1) of this section. In addition, each Board of Medical Examiners must simultaneously report this information to the appropriate state licensing board in the state in which the health care entity is located, if the Board of Medical Examiners is not such licensing board.

(c) *Sanctions.* (1) *Health care entities.* If the Secretary has reason to believe that a health care entity has substantially failed to report information in accordance with this section, the Secretary will conduct an investigation. If the investigation shows that the health care entity has not complied with this section, the Secretary will provide the entity with a written notice describing the noncompliance, giving the health care entity an opportunity to correct the noncompliance, and stating that the entity may request, within 30 days after receipt of such notice, a hearing with respect to the noncompliance. The request for a hearing must contain a statement of the material factual issues in dispute to demonstrate that there is cause for a hearing. These issues must be both substantive and relevant. The hearing will be held in the Washington, DC, metropolitan area. The Secretary will deny a hearing if:

(i) The request for a hearing is untimely,

(ii) The health care entity does not provide a statement of material factual issues in dispute, or

(iii) The statement of factual issues in dispute is frivolous or inconsequential.

In the event that the Secretary denies a hearing, the Secretary will send a written denial to the health care entity setting forth the reasons for denial. If a hearing is denied, or, if as a result of the hearing the entity is found to be in noncompliance, the Secretary will publish the name of the health care entity in the **Federal Register**. In such case, the immunity protections provided under section 411(a) of HCQIA will not apply to the health care entity for professional review activities that occur during the 3-year period beginning 30 days after the date of publication of the entity's name in the **Federal Register**.

(2) *Board of Medical Examiners.* If, after notice of noncompliance and providing opportunity to correct noncompliance, the Secretary determines that a Board of Medical Examiners has failed to report information in accordance with paragraph (b) of this section, the Secretary will designate another qualified entity for the reporting of this information.

§ 60.13 Reporting Federal or state criminal convictions related to the delivery of a health care item or service.

(a) *Who must report.* Federal and state prosecutors must report criminal convictions against health care practitioners, providers, and suppliers related to the delivery of a health care item or service (regardless of whether the conviction is the subject of a pending appeal).

(b) *What information must be reported.* Entities described in paragraph (a) of this section must report the following information:

(1) If the subject is an individual, personal identifiers, including:

(i) Name,

(ii) Social Security Number (or ITIN) (states must report this information, if known, and if obtained in accordance with section 7 of the Privacy Act of 1974),

(iii) Home address or address of record,

(iv) Sex, and

(v) Date of birth.

(2) If the subject is an individual, that individual's employment or professional identifiers, including:

(i) Organization name and type,

(ii) Occupation and specialty, if applicable, and

(iii) National Provider Identifier (NPI).

(3) If the subject is an organization, identifiers, including:

(i) Name,

(ii) Business address,

(iii) Federal Employer Number (FEIN), or Social Security Number (or ITIN) when used by the subject as a Taxpayer Identification Number (TIN),

(iv) The NPI, and

(v) Type of organization.

(4) For all subjects:

(i) A narrative description of the acts or omissions and injuries upon which the reported action was based,

(ii) Classification of the acts or omissions in accordance with a reporting code adopted by the Secretary,

(iii) Name and location of court or judicial venue in which the action was taken,

(iv) Docket or court file number,

(v) Type of action taken,

(vi) Statutory offense(s) and count(s),

(vii) Name of primary prosecuting agency (or the plaintiff in civil actions),

(viii) Date of sentence or judgment,

(ix) Length of incarceration, detention, probation, community service, or suspended sentence,

(x) Amounts of any monetary judgment, penalty, fine, assessment, or restitution,

(xi) Other sentence, judgment, or orders,

(xii) If the action is on appeal,

(xiii) Name and address of the reporting entity, and

(xiv) The name, title, and telephone number of the responsible official submitting the report on behalf of the reporting entity.

(c) *What information may be reported, if known.* Entities described in paragraph (a) of this section and each state should report, if known, the following information:

(1) If the subject is an individual, personal identifiers, including:

(i) Other name(s) used,

(ii) Other address(es), and

(iii) FEIN, when used by the individual as a TIN.

(2) If the subject is an individual, that individual's employment or professional identifiers, including:

(i) State professional license (including professional certification and registration) number(s), field(s) of licensure, and the name(s) of the state or territory in which the license is held,

(ii) Other numbers assigned by Federal or state agencies, to include, but not limited to DEA registration number(s), Unique Physician Identification Number(s) (UPIN), and Medicaid and Medicare provider number(s);

(iii) Name(s) and address(es) of any health care entity with which the subject is affiliated or associated, and

(iv) Nature of the subject's relationship to each associated or affiliated health care entity.

(3) If the subject is an organization, identifiers, including:

(i) Other name(s) used,

(ii) Other address(es) used,

(iii) Other FEIN(s) or Social Security Numbers(s) (or ITINs) used,

(iv) Other NPI(s) used,

(v) State license (including certification and registration) number(s) and the name(s) of the state or territory in which the license is held,

(vi) Other numbers assigned by Federal or state agencies, to include, but not limited to DEA registration number(s), Clinical Laboratory Improvement Act (CLIA) number(s), Food and Drug Administration (FDA) number(s), and Medicaid and Medicare provider number(s),

(vii) Names and titles of principal officers and owners,

(viii) Name(s) and address(es) of any health care entity with which the subject is affiliated or associated, and

(ix) Nature of the subject's relationship to each associated or affiliated health care entity.

(4) For all subjects:

(i) Prosecuting agency's case number,

(ii) Investigative agencies involved,

(iii) Investigative agencies case or file number(s), and

(iv) The date of appeal, if any.

(d) *Access to documents.* Each state must provide the Secretary (or an entity designated by the Secretary) with access to the documents underlying the actions described in paragraphs (a)(1) through (4) of this section, as may be necessary for the Secretary to determine the facts and circumstances concerning the actions and determinations for the purpose of carrying out section 1921.

(e) *Sanctions for failure to report.* The Secretary will provide for publication of a public report that identifies those agencies that have failed to report information on criminal convictions as required to be reported under this section.

§ 60.14 Reporting civil judgments related to the delivery of a health care item or service.

(a) *Who must report.* Federal and state attorneys and health plans must report civil judgments against health care practitioners, providers, or suppliers related to the delivery of a health care item or service (regardless of whether the civil judgment is the subject of a pending appeal). If a government agency is party to a multi-claimant civil judgment, it must assume the responsibility for reporting the entire action, including all amounts awarded to all the claimants, both public and private. If there is no government agency as a party, but there are multiple health plans as claimants, the health plan which receives the largest award must be responsible for reporting the total action for all parties.

(b) *What information must be reported.* Entities described in paragraph (a) of this section must report the information as required in § 60.13(b) of this part.

(c) *What information may be reported, if known.* Entities described in paragraph (a) of this section should report, if known the information as described in § 60.13(c) of this part.

(d) *Access to documents.* Each state must provide the Secretary (or an entity designated by the Secretary) with access to the documents underlying the actions described in paragraphs (a)(1) through (4) of this section, as may be necessary for the Secretary to determine the facts and circumstances concerning the actions and determinations for the purpose of carrying out section 1921.

(e) *Sanctions for failure to report.* Any health plan that fails to report information on a civil judgment required to be reported under this section will be subject to a civil money penalty (CMP) of not more than $25,000 for each such adverse action not reported. Such penalty will be imposed and collected in the same manner as CMPs under subsection (a) of section 1128A of the Social Security Act. The Secretary will provide for publication of a public report that identifies those government agencies that have failed to report information on civil judgments as required to be reported under this section.

§ 60.15 Reporting exclusions from participation in government health care programs.

(a) *Who must report.* Federal Government agencies and state law and fraud enforcement agencies must report health care practitioners, providers, or suppliers excluded from participating in government health care programs, including exclusions that were made in a matter in which there was also a settlement that is not reported because no findings or admissions of liability have been made (regardless of whether the exclusion is the subject of a pending appeal).

(b) *What information must be reported.* Entities described in paragraph (a) of this section must report the following information:

(1) If the subject is an individual, personal identifiers, including:

(i) Name,

(ii) Social Security Number (or ITIN) (state law and fraud enforcement agencies must report this information if known, and if obtained in accordance with section 7 of the Privacy Act of 1974),

(iii) Home address or address of record,

(iv) Sex, and

(v) Date of birth.

(2) If the subject is an individual, that individual's employment or professional identifiers, including:

(i) Organization name and type,

(ii) Occupation and specialty, if applicable, and

(iii) National Provider Identifier (NPI).

(3) If the subject is an organization, identifiers, including:

(i) Name,

(ii) Business address,

(iii) Federal Employer Identification Number (FEIN) or Social Security Number (or ITIN) when used by the subject as a Taxpayer Identification Number (TIN),

(iv) The NPI, and

(v) Type of organization.

(4) For all subjects:

(i) A narrative description of the acts or omissions and injuries upon which the reported action was based,

(ii) Classification of the acts or omissions in accordance with a reporting code adopted by the Secretary,

(iii) Classification of the action taken in accordance with a reporting code adopted by the Secretary, and the amount of any monetary penalty resulting from the reported action,

(iv) The date the action was taken, its effective date and duration,

(v) If the action is on appeal,

(vi) Name of the agency taking the action,

(vii) Name and address of the reporting entity, and

(viii) The name, title, and telephone number of the responsible official submitting the report on behalf of the reporting entity.

(c) *What information may be reported, if known.* Entities described in paragraph (a) of this section should report, if known, the following information:

(1) If the subject is an individual, personal identifiers, including:

(i) Other name(s) used,

(ii) Other address(es),

(iii) FEIN, when used by the individual as a TIN,

(iv) Name of each professional school attended and year of graduation, and

(v) If deceased, date of death.

(2) If the subject is an individual, that individual's employment or professional identifiers, including:

(i) State professional license (including professional registration and certification) number(s), field(s) of licensure, and the name(s) of the state or territory in which the license is held,

(ii) Other numbers assigned by Federal or state agencies, to include, but not limited to DEA registration number(s), Unique Physician Identification Number(s) (UPIN), and Medicaid and Medicare provider number(s),

(iii) Name(s) and address(es) of any health care entity with which the subject is affiliated or associated, and

(iv) Nature of the subject's relationship to each associated or affiliated health care entity.

(3) If the subject is an organization, identifiers, including:

(i) Other name(s) used,

(ii) Other address(es) used,

(iii) Other FEIN(s) or Social Security Numbers(s) (or ITINs) used,

(iv) Other NPI(s) used,

(v) State license (including registration and certification) number(s) and the name(s) of the state or territory in which the license is held,

(vi) Other numbers assigned by Federal or state agencies, to include, but not limited to DEA registration number(s), Clinical Laboratory Improvement Act (CLIA) number(s), Food and Drug Administration (FDA) number(s), and Medicaid and Medicare provider number(s),

(vii) Names and titles of principal officers and owners,

(viii) Name(s) and address(es) of any health care entity with which the subject is affiliated or associated, and

(ix) Nature of the subject's relationship to each associated or affiliated health care entity.

(4) For all subjects:

(i) If the subject will be automatically reinstated, and

(ii) The date of appeal, if any.

(d) *Access to documents.* Each state must provide the Secretary (or an entity designated by the Secretary) with access to the documents underlying the actions described in paragraphs (a)(1) through (4) of this section, as may be necessary for the Secretary to determine the facts and circumstances concerning the actions and determinations for the purpose of carrying out section 1921.

(e) *Sanctions for failure to report.* The Secretary will provide for publication of a public report that identifies those government agencies that have failed to report information on exclusions or debarments as required to be reported under this section.

§ 60.16 Reporting other adjudicated actions or decisions.

(a) *Who must report.* Federal Government agencies, state law or fraud enforcement agencies, and health plans must report other adjudicated actions or decisions as defined in § 60.3 of this part related to the delivery, payment or provision of a health care item or service against health care practitioners, providers, and suppliers (regardless of whether the other adjudicated action or decision is subject to a pending appeal).

(b) *What information must be reported.* Entities described in paragraph (a) of this section must report the information as required in § 60.15(b) of this part.

(c) *What information may be reported, if known.* Entities described in paragraph (a) of this section should report, if known, the information as described in § 60.15(c) of this part.

(d) *Access to documents.* Each state must provide the Secretary (or an entity designated by the Secretary) with access to the documents underlying the actions described in paragraphs (a)(1) through (4) of this section, as may be necessary for the Secretary to determine the facts and circumstances concerning the actions and determinations for the purpose of carrying out section 1921.

(e) *Sanctions for failure to report.* Any health plan that fails to report information on another adjudicated action or decision required to be reported under this section will be subject to a civil money penalty (CMP) of not more than $25,000 for each such action not reported. Such penalty will be imposed and collected in the same manner as CMPs under subsection (a) of section 1128A of the Social Security Act. The Secretary will provide for publication of a public report that identifies those government agencies that have failed to report information on other adjudicated actions as required to be reported under this section.

Subpart C—Disclosure of Information by the National Practitioner Data Bank

§ 60.17 Information which hospitals must request from the National Practitioner Data Bank.

(a) *When information must be requested.* Each hospital, either directly or through an authorized agent, must request information from the NPDB concerning a health care practitioner, as follows:

(1) At the time a health care practitioner, applies for a position on its medical staff (courtesy or otherwise), or for clinical privileges at the hospital; and

(2) Every 2 years concerning any health care practitioner, who is on its medical staff (courtesy or otherwise) or has clinical privileges at the hospital.

(b) *Failure to request information.* Any hospital which does not request the information as required in paragraph (a) of this section is presumed to have knowledge of any information reported to the NPDB concerning this health care practitioner.

(c) *Reliance on the obtained information.* Each hospital may rely upon the information provided by the NPDB to the hospital. A hospital shall not be held liable for this reliance

unless the hospital has knowledge that the information provided was false.

§ 60.18 Requesting information from the National Practitioner Data Bank.

(a) *Who may request information and what information may be available.* Information in the NPDB will be available, upon request, to the persons or entities, or their authorized agents, as described below:

(1) Information reported under §§ 60.7, 60.8, and 60.12 of this part is available to:

(i) A hospital that requests information concerning a health care practitioner who is on its medical staff (courtesy or otherwise) or has clinical privileges at the hospital,

(ii) A health care practitioner who requests information concerning himself or herself,

(iii) A State Medical Board of Examiners or other state authority that licenses health care practitioners,

(iv) A health care entity which has entered or may be entering into an employment or affiliation relationship with a health care practitioner, or to which the health care practitioner has applied for clinical privileges or appointment to the medical staff,

(v) An attorney, or individual representing himself or herself, who has filed a medical malpractice action or claim in a state or Federal court or other adjudicative body against a hospital, and who requests information regarding a specific health care practitioner who is also named in the action or claim. This information will be disclosed only upon the submission of evidence that the hospital failed to request information from the NPDB, as required by § 60.17(a) of this part, and may be used solely with respect to litigation resulting from the action or claim against the hospital,

(vi) A health care entity with respect to professional review activity, and

(vii) A person or entity requesting statistical information, in a form which does not permit the identification of any individual or entity.

(2) Information reported under §§ 60.9, 60.10, 60.11, 60.13, 60.14, 60.15, and 60.16 of this part is available to the agencies, authorities, and officials listed below that request information on licensure or certification actions, any other negative actions or findings, or final adverse actions concerning an individual practitioner, health care entity, provider, or supplier. These agencies, authorities, and officials may obtain data for the purposes of determining the fitness of individuals to provide health care services, protecting the health and safety of individuals receiving health care through programs administered by the requesting agency, and protecting the fiscal integrity of these programs.

(i) Agencies administering (including those providing payment for services) government health care programs, including private entities administering such programs under contract,

(ii) State licensing or certification agencies and Federal agencies responsible for the licensing and certification of health care practitioners, providers, or suppliers,

(iii) State agencies administering or supervising the administration of government health care programs (as defined in 42 U.S.C. 1128(h)),

(iv) State law or fraud enforcement agencies,

(v) Law enforcement officials and agencies such as:

(A) United States Attorney General,

(B) United States Chief Postal Inspector,

(C) United States Inspectors General;

(D) United States Attorneys,

(E) United States Comptroller General,

(F) United States Drug Enforcement Administration,

(G) United States Nuclear Regulatory Commission, or

(H) Federal Bureau of Investigation,

(vi) Utilization and quality control peer review organizations described in part B of title XI and to appropriate entities with contracts under section 1154(a)(4)(C) of the Social Security Act with respect to eligible organizations reviewed under the contracts, but only with respect to information provided pursuant to §§ 60.9 and 60.11 of this part, as well as information provided pursuant to §§ 60.13, 60.14, 60.15, and 60.16 of this part by Federal agencies and health plans,

(vii) Hospitals and other health care entities (as defined in section 431 of the Health Care Quality Improvement Act of 1986), with respect to health care practitioners who have entered (or may be entering) into employment or affiliation relationships with, or have applied for clinical privileges or appointments to the medical staff of such hospitals or other health care entities, but only with respect to information provided pursuant to §§ 60.9 and 60.11, as well as information provided pursuant to §§ 60.13, 60.14, 60.15, and 60.16 by Federal agencies and health plans,

(viii) Health plans,

(ix) A health care practitioner, health care entity, provider, or supplier who requests information concerning himself, herself, or itself, and

(x) A person or entity requesting statistical information, in a form which does not permit the identification of any individual or entity. (For example, researchers may use statistical information to identify the total number of nurses with adverse licensure actions in a specific state. Similarly, researchers may use statistical information to identify the total number of health care entities denied accreditation.)

(b) *Procedures for obtaining National Practitioner Data Bank information.* Persons and entities may obtain information from the NPDB by submitting a request in such form and manner as the Secretary may prescribe. These requests are subject to fees as described in § 60.19 of this part.

§ 60.19 Fees applicable to requests for information.

(a) *Policy on fees.* The fees described in this section apply to all requests for information from the NPDB. The amount of such fees will be sufficient to recover the full costs of operating the NPDB. The actual fees will be announced by the Secretary in periodic notices in the **Federal Register**. However, for purposes of verification and dispute resolution at the time the report is accepted, the NPDB will provide a copy—at the time a report has been submitted, automatically, without a request and free of charge, of the record to the health care practitioner, entity, provider, or supplier who is the subject of the report and to the reporter.

(b) *Criteria for determining the fee.* The amount of each fee will be determined based on the following criteria:

(1) Direct and indirect personnel costs, including salaries and fringe benefits such as medical insurance and retirement,

(2) Physical overhead, consulting, and other indirect costs (including materials and supplies, utilities, insurance, travel, and rent and depreciation on land, buildings, and equipment),

(3) Agency management and supervisory costs,

(4) Costs of enforcement, research, and establishment of regulations and guidance,

(5) Use of electronic data processing equipment to collect and maintain information—the actual cost of the service, including computer search time, runs and printouts, and

(6) Any other direct or indirect costs related to the provision of services.

(c) *Assessing and collecting fees.* The Secretary will announce through notice in the **Federal Register** from time to time the methods of payment of NPDB fees. In determining these methods, the Secretary will consider efficiency, effectiveness, and convenience for the

NPDB users and the Department. Methods may include: credit card, electronic fund transfer, and other methods of electronic payment.

§ 60.20 Confidentiality of National Practitioner Data Bank information.

(a) *Limitations on disclosure.* Information reported to the NPDB is considered confidential and shall not be disclosed outside the Department of Health and Human Services, except as specified in §§ 60.17, 60.18, and 60.21 of this part. Persons and entities receiving information from the NPDB, either directly or from another party, must use it solely with respect to the purpose for which it was provided. The Data Bank report may not be disclosed, but nothing in this section will prevent the disclosure of information by a party from its own files used to create such reports where disclosure is otherwise authorized under applicable state or Federal law.

(b) *Penalty for violations.* Any person who violates paragraph (a) of this section shall be subject to a civil money penalty of up to $11,000 for each violation. This penalty will be imposed pursuant to procedures at 42 CFR part 1003.

§ 60.21 How to dispute the accuracy of National Practitioner Data Bank information.

(a) *Who may dispute the NPDB information.* The NPDB will routinely mail or transmit electronically to the subject a copy of the report filed in the NPDB. In addition, as indicated in § 60.18, the subject may also request a copy of such report. The subject of the report or a designated representative may dispute the accuracy of a report concerning himself, herself, or itself as set forth in paragraph (b) of this section.

(b) *Procedures for disputing a report with the reporting entity.* (1) If the subject disagrees with the reported information, the subject must request in the format as determined by the Secretary that the NPDB enter the report into ''disputed status.''

(2) The NPDB will send the report, with a notation that the report has been placed in ''disputed status,'' to queriers (where identifiable), the reporting entity and the subject of the report.

(3) The subject must attempt to enter into discussion with the reporting entity to resolve the dispute. If the reporting entity revises the information originally submitted to the NPDB, the NPDB will notify the subject and all entities to whom reports have been sent that the original information has been revised. If the reporting entity does not revise the reported information, or does not respond to the subject within 60 days, the subject may request that the Secretary review the report for accuracy. The Secretary will decide whether to correct the report within 30 days of the request. This time frame may be extended for good cause. The subject also may provide a statement to the NPDB, either directly or through a designated representative that will permanently append the report.

(c) *Procedures for requesting a review of a disputed report.* (1) The subject must request, in the format as determined by the Secretary, that the Secretary review the report for accuracy. The subject must return this request to the NPDB along with appropriate materials that support the subject's position. The Secretary will only review the accuracy of the reported information, and will not consider the merits or appropriateness of the action or the due process that the subject received.

(2) After the review, if the Secretary:

(i) Concludes that the information is accurate and reportable to the NPDB, the Secretary will inform the subject and the NPDB of the determination. The Secretary will include a brief statement (Secretarial Statement) in the report that describes the basis for the decision. The report will be removed from ''disputed status.'' The NPDB will distribute the corrected report and statement(s) to previous queriers (where identifiable), the reporting entity and the subject of the report.

(ii) Concludes that the information contained in the report is inaccurate, the Secretary will inform the subject of the determination and direct the NPDB or the reporting entity to revise the report. The Secretary will include a brief statement (Secretarial Statement) in the report describing the findings. The NPDB will distribute the corrected report and statement(s) to previous queriers (where identifiable), the reporting entity and the subject of the report.

(iii) Determines that the disputed issues are outside the scope of the Department's review, the Secretary will inform the subject and the NPDB of the determination. The Secretary will include a brief statement (Secretarial Statement) in the report describing the findings. The report will be removed from ''disputed status.'' The NPDB will distribute the report and the statement(s) to previous queriers (where identifiable), the reporting entity and the subject of the report.

(iv) Determines that the adverse action was not reportable and therefore should be removed from the NPDB, the Secretary will inform the subject and direct the NPDB to void the report. The NPDB will distribute a notice to previous queriers (where identifiable), the reporting entity and the subject of the report that the report has been voided.

§ 60.22 Immunity.

Individuals, entities or their authorized agents, and the NPDB shall not be held liable in any civil action filed by the subject of a report unless the individual, entity, or authorized agent submitting the report has actual knowledge of the falsity of the information contained in the report.

PART 61—[REMOVED]

■ 2. Under the authority of 42 U.S.C. 1320a–7e, remove part 61.

[FR Doc. 2013–07521 Filed 4–4–13; 8:45 am]

BILLING CODE 4165–15–P

Proposed Rules

Federal Register
Vol. 78, No. 66
Friday, April 5, 2013

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 COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 130128081–3297–01]

RIN 0648–BC96

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Commercial Trap Sectors of the Reef Fish and Spiny Lobster Fisheries in the U.S. Caribbean; Control Date

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

ACTION: Advance notice of proposed rulemaking; consideration of a control date.

SUMMARY: NMFS announces that it is establishing a control date of February 10, 2011, to control future access to the commercial trap sectors of the reef fish and spiny lobster fisheries operating in the exclusive economic zone (EEZ) of the U.S. Caribbean. If changes to the management regime are developed and implemented under the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), a control date could be used to limit the number of participants in these sectors. This announcement is intended, in part, to promote awareness of the potential eligibility criteria for future access so as to discourage speculative entry into the trap sectors while the Caribbean Fishery Management Council (Council) and NMFS consider whether and how access to the commercial trap sectors of the reef fish and spiny lobster fisheries should be controlled.

DATES: Written comments must be received on or before May 6, 2013.

ADDRESSES: You may submit comments, identified by ''NOAA–NMFS–2013–0022'' by any one of the following methods:

- *Electronic submissions:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2013-0022*, click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit written comments to Britni Tokotch, Southeast Regional Office, NMFS, 263 13th Avenue South, St. Petersburg, FL 33701.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous). Attachments to electronic comments will be accepted in Microsoft Word, Excel, or Adobe PDF file formats only.

FOR FURTHER INFORMATION CONTACT: Britni Tokotch, Southeast Regional Office, NMFS, telephone 727–824–5305, email: *britni.tokotch@noaa.gov.*

SUPPLEMENTARY INFORMATION: At the August 2012 Council meeting, the Council recommended a control date of February 10, 2011, for the commercial trap sectors of the reef fish and spiny lobster fisheries in the U.S. Caribbean. The control date would apply to persons who are contemplating entering these trap sectors.

Previously, the Council established a control date of March 24, 2009, for the commercial sector of the reef fish, queen conch, and spiny lobster fisheries operating in Federal waters off Puerto Rico and the U.S. Virgin Islands (USVI). Subsequent to that action, the USVI began development of trap reduction programs and established a February 10, 2011, control date. At the August 2012 meeting, the Council discussed the ongoing development of trap reduction programs in the USVI, which if approved and implemented, would preserve and protect the historical and cultural fish trap sectors in a sustainable manner by reducing the total number of traps. To be consistent with the territorial regulations, the Council voted to update the previous control date of March 24, 2009, and establish a February 10, 2011, control date for the commercial trap sectors of the reef fish and spiny lobster fisheries of the U.S. Caribbean.

The Council requested that this control date be published in the **Federal Register** to notify fishermen that if they entered such a sector after February 10, 2011, they may not be assured of future access if the Council and/or NMFS decide to limit entry or impose other measures to manage these trap sectors.

Establishment of this control date does not commit the Council or NMFS to any particular management regime or criteria for entry into the commercial trap sectors of the reef fish and spiny lobster fisheries. Fishermen are not guaranteed future participation in the sectors regardless of their level of participation before or after the control date. The Council may recommend a different control date or it may recommend a management regime that does not involve a control date. Other criteria, such as documentation of landings or fishing effort, may be used to determine eligibility for participation in a limited access fishery or sector. The Council and/or NMFS also may choose to take no further action to control entry or access to the sectors, in which case the control date may be rescinded. Any action by the Council will be taken pursuant to the requirements for fishery management plan and amendment development established under the Magnuson-Stevens Act.

This notification also gives the public notice that interested participants should locate and preserve records that substantiate and verify their participation in the commercial trap sectors of the reef fish and spiny lobster fisheries in the U.S. Caribbean EEZ.

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

Dated: April 2, 2013.

Alan D. Risenhoover,

Director, Office of Sustainable Fisheries, performing the functions and duties of the Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2013–07991 Filed 4–4–13; 8:45 am]

BILLING CODE 3510–22–P

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 733

RIN 3206–AM80

Political Activity—Federal Employees Residing in Designated Localities

AGENCY: Office of Personnel Management.

ACTION: Proposed rule.

SUMMARY: The Office of Personnel Management (OPM) proposes to amend its regulations by granting Federal employees residing in the District of Columbia a partial exemption from the political activity restrictions and adding the District of Columbia to its regulatory list of designated localities. The proposed amendment reflects OPM's determination that the District of Columbia meets the criteria for a partial exemption to issue.

DATES: Written comments must be received on or before June 4, 2013.

ADDRESSES: Comments may be mailed to Elaine Kaplan, General Counsel, Room 7355, United States Office of Personnel Management, 1900 E Street NW., Washington, DC 20415.

FOR FURTHER INFORMATION CONTACT: Jo-Ann Chabot, Office of the General Counsel, United States Office of Personnel Management, (202) 606–1700.

SUPPLEMENTARY INFORMATION: The Hatch Act, at 5 U.S.C. 7321–7326, governs the political activity of Federal employees, as well as individuals employed with the United States Postal Service. Section 7323(a) generally permits Federal employees who are not employed in the Federal agencies or positions described in section 7323(b), as amended, to take an active part in partisan political campaigns. Employees employed in the Federal agencies or positions specified in 5 U.S.C. 7323(b), as amended, generally may participate in nonpartisan political activities. According to 5 U.S.C. 7323(a)(2) and (3), Federal employees may not become candidates for partisan political office and may not solicit, accept, or receive political contributions. Section 7325, however, authorizes OPM to prescribe regulations exempting Federal employees from the prohibitions in section 7323(a)(2) and (3) to the extent OPM considers it to be in their domestic interest.

Under the authority of 5 U.S.C. 7325, as amended, OPM may issue a regulatory exemption to the District of Columbia if OPM determines that, because of special or unusual circumstances, it is in the domestic interest of the District's federally employed residents to permit their political participation in accordance with regulations prescribed by OPM.

In regulations at 5 CFR 733.107(c), OPM has designated municipalities and political subdivisions where Federal employees may participate in local elections. At 5 CFR 733.103–733.106, OPM has established limitations on political participation by most Federal employees residing in these designated municipalities and subdivisions. Under 5 CFR 733.103, most Federal employees who reside in a municipality or political subdivision designated by OPM may: (1) Run as an independent candidate in a local election to partisan political office; (2) solicit, accept, or receive political contributions as, or on behalf of, an independent candidate for partisan political office in a local election; (3) accept or receive political contributions on behalf of an individual who is a candidate for local partisan political office and who represents a political party; (4) solicit, accept, or receive uncompensated volunteer services as an independent candidate, or on behalf of an independent candidate, for local partisan political office; and (5) solicit, accept, or receive uncompensated volunteer services on behalf of an individual who is a candidate for local partisan political office and who represents a political party.

Under 5 CFR 733.104, however, these employees may not: (1) Run as the representative of a political party for local partisan political office; (2) solicit political contributions on behalf of individuals who are candidates for local partisan political office and who represent a political party; (3) knowingly solicit a political contribution from any Federal employee, except when permitted; (4) accept or receive political contributions from a subordinate; (5) solicit, accept, or receive uncompensated volunteer services from a subordinate for any political purpose. Employees also may not participate in political activities when on duty, or while they are wearing items that identify their employing agency or their position. They cannot participate in political activities while they are in any room or building in the discharge of official duties by an individual employed or holding office in the Government of the United States or any agency or instrumentality thereof; nor while using a Government-owned or lease vehicle, or while using a privately-owned vehicle in the discharge of official duties.

Moreover, candidacy for, and service in, a partisan political office shall not result in neglect of, or interference with, the performance of the duties of the employee or create a conflict, or apparent conflict, of interest.

Sections 733.103 and 733.104 of Title 5, Code of Federal Regulations, do not apply to individuals, such as career senior executives and employees of the Federal Bureau of Investigation, who are employed in the agencies or positions listed in 5 U.S.C. 7323(b) and 5 CFR 733.105(a). These individuals are subject to the more stringent limitations described in 5 CFR 733.105 and 733.106.

Individuals who require advice concerning specific political activities, and whether an activity is permitted or prohibited under 5 CFR 733.103–733.106, should contact the United States Office of Special Counsel at (800) 854–2824 or (202) 254–3650. Requests for Hatch Act advisory opinions may be made by email to: *hatchact@osc.gov.*

In response to an application from the Honorable Eleanor Holmes Norton, the Delegate from the District of Columbia to the United States House of Representatives, OPM proposes to designate the District of Columbia as a municipality in which Federal employees may run for local partisan political office, subject to the limitations established by OPM, and accept or receive political contributions in connection with elections for local public office. This proposal reflects OPM's determination that special or unusual circumstances exist so that it is in the domestic interest of Federal employees residing in the District of Columbia to participate in these political activities. Principal factors leading to OPM's determination are the enactment of the Hatch Act Modernization Act of 2012, Public Law 112–230 (December 28, 2012), expressly providing for a partial exemption for the District of Columbia, as well as the District of Columbia's high concentration of federally employed residents, its unique position as the capital of the United States, and the partisan nature of its elections for local public office.

If this proposed rule is adopted, OPM will amend 5 CFR 733.107(c) by adding the District of Columbia to the list of other designated municipalities in which Federal Government employees may participate in elections for local partisan political office in accordance with the conditions specified in 5 CFR 733.103—733.106. The addition of the District of Columbia will be listed after Crane, Indiana, and before Elmer City, Washington.

E.O. 12291, Federal Regulation

I have determined that this is not a major rule as defined under section 1(b) of E.O. 12291, Federal Regulation.

Regulatory Flexibility Act

I certify that this regulation will not have a significant economic impact on a substantial number of small entities because the changes will affect only employees of the Federal Government.

List of Subjects in 5 CFR Part 733

Political activity—Federal employees residing in designated localities.

U.S. Office of Personnel Management.

John Berry,

Director.

Accordingly, the Office of Personnel Management proposes to amend 5 CFR Part 733 as follows:

PART 733—POLITICAL ACTIVITY—FEDERAL EMPLOYEES RESIDING IN DESIGNATED LOCALITIES

■ 1. The authority citation for part 733 is revised to read as follows:

Authority: 5 U.S.C. 7325; Pub. L. 112–230 (The Hatch Act Modernization Act of 2012), 126 Stat. 1616 (Dec. 28, 2012); sec. 308 of Pub. L. 104–93, 109 Stat. 961, 966 (Jan. 6, 1996)

■ 2. Section 733.107(c) is amended by adding the District of Columbia, alphabetically, to the list of other designated municipalities as set forth below.

§ 733.107 Designated localities.

* * * * *

(c) * * *

Other Municipalities

* * * * *

District of Columbia

* * * * *

[FR Doc. 2013–07872 Filed 4–4–13; 8:45 am]

BILLING CODE 6325–48–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 2

[NRC–2013–0050]

RIN 3150–AJ24

Potential Changes to Interlocutory Appeals Process for Adjudicatory Decisions

AGENCY: Nuclear Regulatory Commission.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing this Advance Notice of Proposed Rulemaking (ANPR) to begin the process of potentially amending its regulations to change the interlocutory appeals process for certain adjudicatory decisions. The NRC seeks public comment on these potential changes to the interlocutory appeals process.

DATES: Submit comments by July 5, 2013. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration of comments received on or before this date.

ADDRESSES: You may access information and comment submissions related to this ANPR, which the NRC possesses and is publicly available, by searching on *http://www.regulations.gov* under Docket ID NRC–2013–0050. You may submit comments by any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2013–0050. Address questions about NRC dockets to Carol Gallagher; telephone: 301–492–3668; email: *Carol.Gallagher@nrc.gov.*
- *Email comments to: Rulemaking.Comments@nrc.gov.* If you do not receive an automatic email reply confirming receipt, then contact us at 301–415–1677.
- *Fax comments to:* Secretary, U.S. Nuclear Regulatory Commission at 301–415–1101.
- *Mail comments to:* Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attn: Rulemakings and Adjudications Staff.
- *Hand deliver comments to:* 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. (Eastern time) Federal workdays; telephone: 301–415–1677.

For additional direction on accessing information and submitting comments, see ''Accessing Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: James Biggins, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–6305; email: *james.biggins@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Accessing Information and Submitting Comments

A. Accessing Information

Please refer to Docket ID NRC–2013–0050 when contacting the NRC about the availability of information for this ANPR. You may access information related to this ANPR, which the NRC possesses and is publicly available, by the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2013–0050.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may access publicly available documents online in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email at *PDR.Resource@nrc.gov.* The ADAMS accession number for each document referenced in this ANPR (if that document is available in ADAMS) is provided the first time that a document is referenced.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2013–0050 in the subject line of your comment submission, in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *http://www.regulations.gov* and enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submissions. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

II. Additional Information

The NRC is considering four options pertaining to the interlocutory review of rulings on requests for hearings or petitions to intervene under § 2.311 of Title 10 of the *Code of Federal*

Regulations (10 CFR). At the NRC, an interlocutory appeal is a request for the Commission to consider an adjudicatory issue prior to the conclusion of the hearing process before the Atomic Safety and Licensing Board (Licensing Board). The NRC seeks public comments on the four options described in Section B, *Options for Amending the 10 CFR 2.311 Interlocutory Review Provision,* of this document, as well as on its interlocutory appeals rules and process in general.

A. Interlocutory Review Under Current NRC Regulations

The NRC regulations currently provide three avenues for interlocutory review in NRC adjudicatory hearings. First, 10 CFR 2.341(f)(1) provides for interlocutory review of questions certified to the Commission under 10 CFR 2.319(l), or of rulings referred or issues certified to the Commission under 10 CFR 2.323(f). These questions or rulings may be certified to the Commission by the presiding officer in his or her discretion, or on the motion of a party requesting that the presiding officer exercise this discretion. When determining whether to certify such a question or ruling, the presiding officer must find, as a threshold matter that it raises significant and novel legal or policy issues, or the resolution of the issues would materially advance the orderly disposition of the proceeding. Party motions initiating this process must be made no later than 10 days after the occurrence or circumstance from which the motion arises.

Second, 10 CFR 2.341(f)(2) allows a party to directly request interlocutory review of the Commission without referral or certification by the presiding officer. Such a request must be filed within 25 days after the decision or action at issue. The request must contain a summary of the decision or action at issue, a statement that the argument in the request was previously raised before the presiding officer, or why it was not, a statement why the decision or action is erroneous, and a statement why Commission review should be exercised. The Commission may grant this interlocutory review in its discretion if, the party requesting review demonstrates that the issue threatens the requesting party with immediate and serious irreparable impact, which could not be alleviated through a petition for review of the final decision, or the issue affects the basic structure of the proceeding in a pervasive or unusual manner.

Third, 10 CFR 2.311 provides an opportunity to request interlocutory review for a limited subset of rulings—requests for hearings or petitions to intervene, selection of hearing procedures, and requests by potential parties for access to sensitive unclassified non-safeguards information or safeguards information. With respect to rulings on requests for hearings or petitions to intervene, the interlocutory appeal must be made within 25 days after the service of the order. The appeal is initiated by filing a notice of appeal and accompanying supporting brief. Unlike the other methods of interlocutory review, these appeals do not require the satisfaction of specific threshold requirements, but they are limited in scope to whether a hearing opportunity should have been granted or wholly denied. Because of this limitation, if at least one of the petitioner's contentions is admitted, meaning that the petitioner has been admitted as a party to the hearing process, then the petitioner may not appeal the denial of any of its other contentions under 10 CFR 2.311; the petitioner may appeal these individual contention admissibility determinations only pursuant to 10 CFR 2.341(f)(1) or (f)(2), or may appeal them pursuant to 10 CFR 2.341(b) after the Licensing Board has issued its final decision. Similarly, parties, such as the license applicant, can immediately appeal the admission of all of the petitioner's admitted contentions under 10 CFR 2.311 on the grounds that *none* of the contentions are admissible, and therefore that there should be no hearing. However, such parties cannot appeal under 10 CFR 2.311 that *some* of the admitted contentions should not have been admitted; the appeal of individual contention admissibility determinations (but fewer than all contentions) may only be made under 10 CFR 2.341(f)(1) or (f)(2) and subject to its threshold requirements. The result of the interlocutory appeal process under § 2.311 is that the Commission determines whether or not a hearing opportunity should have been granted at all.

In summary, three processes exist for interlocutory review in the current NRC regulations, each with its own threshold requirements: (1) Certified interlocutory reviews allow a party to request that the presiding officer certify an issue to the Commission. The threshold for Commission consideration is that the certified issue must raise significant and novel legal or policy issues, and the resolution of the issues would materially advance the orderly disposition of the proceeding; (2) Direct interlocutory reviews to the Commission under § 2.341(f)(2). The threshold requirement for acceptance of the appeal is that the party must be threatened with immediate and serious irreparable impact, which could not be alleviated through a petition for review of the final decision, or the issue affects the basic structure of the proceeding in a pervasive or unusual manner; and (3) Interlocutory review under § 2.311 that has no threshold requirements. However, the scope of such a review, with respect to requests for hearings or petitions to intervene, is limited to whether there is standing and at least one admissible contention so that the petitioner should be granted a hearing and made a party to a proceeding. Interlocutory review under 10 CFR 2.311 is not available regarding whether specific contentions should have been admitted or denied, but only regarding whether at least one contention should have been admitted or all contentions denied and, thus, admission to a hearing proceeding should be granted or denied.

B. Options for Amending the 10 CFR 2.311 Interlocutory Review Provision

The NRC is considering four options with respect to the interlocutory review of rulings on requests for hearings or petitions to intervene: (1) Retaining the current rule without any change (status quo), which permits interlocutory appeals, without any threshold requirements, of rulings on requests for hearings or petitions to intervene regarding only whether the hearing or intervention should be granted or denied in its entirety; (2) Increasing the scope of 10 CFR 2.311 beyond just whether the hearing or intervention should be granted or denied in its entirety to encompass the interlocutory review of each individual contention admissibility determination. All appeals would have to be made immediately following the issuance of the ruling by the presiding officer; (3) Increasing the scope of 10 CFR 2.311 to encompass the interlocutory review of each individual contention admissibility determination, except for the admission or denial of contentions grounded in the National Environmental Policy Act of 1969, as amended (NEPA). For decisions on environmental contentions partially admitting or partially denying a request or petition, the appeal of which would only be entertained either (a) after the issuance of a final Environmental Impact Statement (or other NEPA document) or, alternatively, (b) after a final decision in the proceeding (non-interlocutory); and (4) Reducing the scope of 10 CFR 2.311 to include only interlocutory review of whether a request for hearing or petition to intervene was properly denied in its

entirety. Orders granting a hearing, but only admitting some contentions would not be immediately appealable by any party. In addition to these options, the NRC seeks comment on clarifying the interlocutory review process.

Option 1

Option 1 is to retain the status quo. The current language of 10 CFR 2.311 has been in place since 1972 (37 FR 28,710; December 29, 1972). Section 2.311 makes immediately appealable, without threshold requirements, the granting or denial of a request for hearing or petition to intervene, but not the granting or denial of individual contentions. Therefore, a party whose request or petition has been granted by a finding of standing and the admission of at least one contention is not allowed to immediately appeal the order denying its other contentions under 10 CFR 2.311. Conversely, a party in opposition to the granted request or petition may argue on immediate appeal under 10 CFR 2.311 only that none of the contentions should have been admitted and thus, the request or petition should have been wholly denied; it cannot argue that only some of the admitted contentions should not have been admitted. Interlocutory appeals of individual contention admissibility determinations not necessary for the granting or denial of a request or petition must be made according to the interlocutory review requirements of 10 CFR 2.341(f)(1) or (f)(2), respectively, or await the final decision of the Licensing Board on the admitted contentions. Unlike 10 CFR 2.311, these interlocutory review processes have specific threshold requirements.

The arguable advantage of the current limited scope of 10 CFR 2.311 is that it provides for immediate appeal, without threshold requirements, of the most crucial determination, which is whether a party is admitted to a proceeding, but imposes the threshold requirements for other interlocutory appeals on individual contention admissibility determinations that do not affect whether the party is admitted to the proceeding. Applying threshold requirements to these individual contention admissibility determinations may save the Commission from attending to matters that, by the end of the proceeding, prove to no longer be an issue. One disadvantage of the current rule is that if a petitioner appeals its denied contentions under § 2.341(b) after the Licensing Board concludes the hearing process, the Commission could grant the appeal and remand the proceeding to the Licensing Board to consider a contention that was originally denied. This scenario re-starts the hearing process for the remanded issue and extends the length of the proceeding. Another arguable disadvantage of 10 CFR 2.311 as currently written is that it may encourage parties opposing the request or petition to appeal admission of all contentions, regardless of merit, in order to preserve their right to appeal individual contention admissibility determinations under the advantageous no-threshold standard of 10 CFR 2.311. Conversely, it may prevent individual contentions, which should not have been admitted, to proceed in the hearing process, thereby using hearing resources unnecessarily.

Questions on Option 1

1. Does the current language of 10 CFR 2.311 strike a fair balance between allowing, without threshold requirements, the early resolution of contention admissibility determinations and preserving resources by deferring appellate review of issues?

2. Is it fair that the standard focuses on whether or not a hearing should be granted which results in an opposing party's ability to appeal the admission of all admitted contentions whereas the petitioner's ability to appeal is limited to the denial of all of its contentions?

3. Will Option 1 result in time and resource savings to the parties compared to the other options? Consider whether there are time and resource savings resulting from entertaining only some 10 CFR 2.311 appeals of contention admissibility determinations compared to the risk that the failure to resolve all contention admissibility determinations early in the proceeding will result in the Commission later finding a contention admissible and remanding the issue to the Licensing Board or later finding a contention inadmissible and invalidating the adjudication of a contention.

Option 2

Option 2 is to consider amending 10 CFR 2.311(c) and (d) to allow any petitioner or party to appeal an order granting or denying in whole or in part a request for hearing or petition to intervene within 25 days of the presiding officer's issuance of the order. This amendment would effectively allow all petitioners and parties to immediately appeal, without threshold requirements, rulings on the admissibility of any particular contention (including new or amended contentions filed after the deadline in 10 CFR 2.309(b)). This would be the only opportunity to challenge the ruling. If a petitioner or party failed to challenge the presiding officer's ruling within that 25-day time period, it would not be able to challenge the contention admissibility decision at the end of the proceeding.

The arguable advantage of amending 10 CFR 2.311 in this manner is that it would allow for the early resolution of all contention admissibility determinations. This amendment would eliminate the possibility that, after a Licensing Board has issued its final order in a proceeding, the Commission, on appeal, will remand the proceeding to the Licensing Board for consideration of a previously denied contention that should have been admitted or that the Commission will find an admitted contention to be inadmissible and invalidate the adjudication of the contention in the proceeding. Additionally, since a party other than the petitioner could appeal the admission of individual petitioner contentions instead of the admission of all petitioner contentions, that party may no longer be incentivized to oppose all admitted contentions, including those individual contentions that it may not otherwise oppose, in order to preserve its right to appeal the admission of those individual contentions that it does indeed oppose. The argument against this approach is that the advantages of early resolution of contention admissibility determinations may be outweighed by the increased adjudicatory workload resulting from the ability of all parties to immediately appeal all contention admissibility determinations without threshold requirements. Additionally, this option would require the petitioners and other parties to devote their attention to matters that, under the current rules, the petitioners and parties would not have been asked to address because, in many cases, at the end of a proceeding, parties choose not to appeal decisions denying the admissibility of contentions or a settlement agreement may have obviated the need to address the admissibility question. Licensing Boards and parties may be hesitant to proceed with the hearing process while contention admissibility is being reviewed by the Commission. Currently, the Commission only periodically receives appeals of the denial of contentions following issuance of Licensing Boards' orders at the end of the hearing process. Option 2 could result in significant workload increases for the Commission if all contentions are likely to be appealed in each case.

Questions on Option 2

1. Will the time and resource savings resulting from conducting a proceeding

only after interlocutory appellate review of the admissibility of the contentions outweigh the time and resources that must be devoted to this appellate review by the parties, Licensing Board, and the Commission?

2. Will this change likely result in the immediate appeal of contention admissibility in most or all cases? Consider whether there would be any incentive for parties to not automatically challenge all Licensing Board orders from either perspective of admitting or denying contentions.

3. Would the likely increase in the quantity of appeals result in a commensurate improvement in the efficiency of the adjudicatory process?

4. Will the availability of a no-threshold appeal for all contention admissibility determinations incentivize petitioners and parties to appeal each contention admissibility determination regardless of merit?

Option 3

Option 3 is to amend 10 CFR 2.311(c) and (d) to allow any petitioner or party to appeal an order granting or denying in whole or in part a request for hearing or petition to intervene within 25 days of the presiding officer's issuance of the order with the exception that, when a request or petition is granted in part, the admission or denial of individual environmental contentions cannot be appealed until (a) after the issuance of a final Environmental Impact Statement or, alternatively, until (b) after issuance of the Licensing Board's decision at the end of the hearing process. This alternative would effectively allow all petitioners and parties to immediately appeal, without threshold requirements, rulings on the admissibility of any particular contention (including new or amended contentions filed after the deadline in § 2.309(b)), except for the denial or admission of environmental contentions when a request or petition is granted in part.

The arguable advantages and disadvantages of amending 10 CFR 2.311 to include all contention admissibility determinations under alternative b), are the same as discussed under Option 2. The arguable advantage of specifically excluding the denial or admission of environmental contentions from 10 CFR 2.311 interlocutory review when a request or petition is granted in part is to better align the timing of the review of environmental contentions with the requirements of NEPA. Unlike other contentions, which have to do with the application's satisfaction of NRC regulatory requirements, environmental contentions are concerned with the NRC staff's performance of environmental reviews related to major federal actions as required by NEPA. Generally, when contention admissibility is first determined in a proceeding, these NRC environmental review documents are not yet available. Therefore, at that time, environmental contention admissibility is determined based on an applicant's environmental report. If a request or petition were granted, but one or more of the requestor or petitioner environmental contentions were denied, an immediate appeal of the environmental contentions could potentially become obviated later in time as the content of the NRC staff's environmental document is drafted. For example, the NRC staff's environmental review document could fully address an issue raised by the admitted environmental contention. Thus, a number of unnecessary interlocutory appeals, and their associated resource and time commitments, may be avoided by excluding interlocutory appeals of individual environmental contentions from 10 CFR 2.311 and waiting until after the issuance of the staff's environmental document. The arguable disadvantages of this timing scheme are that contentions which should have been denied continue in the process until the staff's environmental document is issued, or that denied contentions are later admitted by the Commission after the staff's environmental document has been prepared and issued, thus requiring additional staff review outside of the initial process. Additionally, discerning between environmental and non-environmental contentions would become an extra step in the review process.

Questions on Option 3

1. Should contentions grounded in NEPA and related environmental statutes be treated differently than contentions grounded in the Atomic Energy Act of 1954, as amended (AEA), or other requirements, considering that NEPA and the AEA have different requirements?

2. Would petitioners or other parties be prejudiced by treating environmental contentions differently than other contentions?

3. Will the time and resource savings potentially resulting from advancing the appeal of individual contentions, other than environmental contentions, result in efficiencies to the hearing process?

Option 4

Option 4 is to amend 10 CFR 2.311 to only allow for the interlocutory review, without threshold requirements, of a complete denial of a request for a hearing or petition to intervene. Neither the order admitting all contentions, nor the order admitting some and denying some individual contentions would be appealable under 10 CFR 2.311 under this option. These issues would only be immediately appealable according to the interlocutory appeals processes of 10 CFR 2.341(f)(1) or (f)(2), subject to their threshold requirements, or appealable upon the initial decision of the Licensing Board according to the appeals process of 10 CFR 2.341(b).

The arguable advantage of this change is that it would remove the perceived incentive under the current rule for a party to appeal every granted contention, regardless of merit. This option would likely reduce the number of interlocutory appeals, and the resulting expenditure of time and resources to pursue those appeals. The apparent disadvantage would be the removal of the early determination as to the proper admission of some contentions. As previously discussed, without some immediate appellate review of the admission of contentions, the parties may expend significant time and resources only to later have the Commission find the contention to be inadmissible and invalidate the proceeding as it relates to consideration of those contentions. Additionally, this change would allow petitioners to appeal denials of requests and hearings under the no-threshold standard of 10 CFR 2.311, whereas other parties would have to appeal the granting of these requests or hearings under the standards of 10 CFR 2.341, all of which have threshold requirements that must be satisfied.

Questions on Option 4

1. Will the inability to immediately appeal, without threshold requirements, rulings other than complete denials of hearing requests or petitions result in the unnecessary expenditure of time and resources dedicated to resolving a contention that is later determined by the Commission to be inadmissible?

2. Because this option limits interlocutory appeals to situations where a petition is wholly denied, will it result in saved resources from reduced interlocutory appeals, or will it result in those appeals simply being deferred to the final Licensing Board decision, at which time the appeals will be filed?

3. Are the potentially saved resources from limiting interlocutory appeals under this option balanced by the resources potentially spent on adjudicating contentions that should have been denied?

4. Is it fair under this interlocutory appeal option to allow petitioners to appeal a complete denial with no threshold requirements, whereas other parties must appeal pursuant to § 2.341, which has threshold requirements?

Question on Clarifying the Interlocutory Review Process

In examining any of the potential options there is an additional question on which the agency invites comments. This question relates to a potential clarifying reorganization of the interlocutory appeal provisions rather than to change the substance of those requirements.

1. Currently, the authority to seek interlocutory appeal and the filing requirements to file an appeal are covered in several different sections of the regulations including 10 CFR 2.311, 2.323, and 2.341. Should the provisions governing interlocutory appeals be separate or consolidated in one section in order to provide clarity and consistency?

For the Nuclear Regulatory Commission.

Dated at Rockville, Maryland, this 27th day of March 2013.

Margaret M. Doane,

General Counsel.

[FR Doc. 2013–07960 Filed 4–4–13; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF ENERGY

10 CFR Part 430

[Docket No. EERE–2011–BT–STD–0006]

RIN 1904–AC43

Energy Conservation Program: Availability of the Preliminary Technical Support Document for General Service Fluorescent Lamps and Incandescent Reflector Lamps

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

ACTION: Notice of extension of public comment period.

SUMMARY: On February 28, 2013, the U.S. Department of Energy (DOE) published a notice of public meeting and availability of the preliminary analysis on general service fluorescent lamps (GSFLs) and incandescent reflector lamps (IRLs) energy conservation standards in the **Federal Register**. This notice announces an extension of the public comment period for submitting comments on the preliminary analysis or any other aspect of the rulemaking for GSFLs and IRLs. The comment period is extended to May 13, 2013.

DATES: The comment period for the proposed rule published February 28, 2013, at 78 FR 13563, is extended. DOE will accept comments, data, and other information regarding this proposed rulemaking no later than May 13, 2013.

ADDRESSES: Interested persons may submit comments, identified by docket number EERE–2011–BT–STD–0006 and/or Regulation Identification Number (RIN) 1904–AC43, by any of the following methods:

- *Federal eRulemaking Portal*: *www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: GSFL-IRL_2011-STD-0006@ee.doe.gov*. Include the docket number EERE–2011–BT–STD–0006 and/or RIN 1904–AC43 in the subject line of the message.
- *Mail:* Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Program, Mailstop EE–2J, 1000 Independence Avenue SW., Washington, DC 20585–0121. If possible, please submit all items on a compact disc (CD), in which case it is not necessary to include printed copies. [Please note that comments and CDs sent by mail are often delayed and may be damaged by mail screening processes.]
- *Hand Delivery/Courier:* Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Program, 950 L'Enfant Plaza, SW., Suite 600, Washington, DC 20024. Telephone (202) 586–2945. If possible, please submit all items on CD, in which case it is not necessary to include printed copies.

Docket: The docket is available for review at *www.regulations.gov*, including **Federal Register** notices, framework documents, public meeting attendee lists and transcripts, comments, and other supporting documents/materials. All documents in the docket are listed in the *www.regulations.gov* index. However, not all documents listed in the index may be publicly available, such as information that is exempt from public disclosure.

The rulemaking Web page can be found at: *http://www1.eere.energy.gov/buildings/appliance_standards/rulemaking.aspx/ruleid/24*. This Web page contains links to the preliminary technical support document and other supporting materials and information for this rulemaking on the regulations.gov site. The regulations.gov Web page contains instructions on how to access all documents in the docket, including public comments.

FOR FURTHER INFORMATION CONTACT: Ms. Lucy deButts, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies, EE–2J, 1000 Independence Avenue SW., Washington, DC 20585–0121. Telephone: (202) 287–1604. Email: *general_service_fluorescent_lamps@ee.doe.gov*.

In the Office of the General Counsel, contact Ms. Elizabeth Kohl, U.S. Department of Energy, Office of the General Counsel, GC–71, 1000 Independence Avenue SW., Washington, DC 20585–0121. Telephone: (202) 586–7796. Email: *elizabeth.kohl@hq.doe.gov*.

SUPPLEMENTARY INFORMATION: On February 28, 2013, the U.S. Department of Energy (DOE) published a notice of public meeting and availability of the preliminary analysis in the **Federal Register** (78 FR 13563) to make available and invite comments on the preliminary analysis for general service fluorescent lamps and incandescent reflector lamps energy conservation standards. The notice provided for the submission of comments by April 15, 2013, and comments will also be accepted at a public meeting to be held on April 9, 2013. The Appliance Standards Awareness Project (ASAP) and the National Electrical Manufacturers Association (NEMA) jointly requested a four-week extension of the comment period. ASAP and NEMA stated the additional time was needed for interested parties to consider and respond to the preliminary technical support document and public meeting presentation, and prepare and submit comments accordingly.

DOE has determined that an extension of the public comment period is appropriate based on the foregoing reason and is hereby extending the comment period. DOE will consider any comments received by midnight of May 13, 2013, and deems any comments received by that time to be timely submitted.

Issued in Washington, DC, on April 1, 2013.

Kathleen B. Hogan,

Deputy Assistant Secretary for Energy Efficiency, Energy Efficiency and Renewable Energy.

[FR Doc. 2013–07974 Filed 4–4–13; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

10 CFR Part 431

[Docket No. EERE–2010–BT–STD–0043]

RIN 1904–AC36

Energy Conservation Program: Availability of the Interim Technical Support Document for High-Intensity Discharge Lamps

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

ACTION: Notice of extension of public comment period.

SUMMARY: On February 28, 2013, the U.S. Department of Energy (DOE) published a notice of public meeting and availability of the interim technical support document (TSD) for high-intensity discharge (HID) lamps energy conservation standards in the **Federal Register**. This document announces an extension of the public comment period for submitting comments on the interim TSD or any other aspect of the rulemaking for HID lamps. The comment period is extended to May 17, 2013.

DATES: The comment period for the proposed rule published February 28, 2013, at 78 FR 13566, is extended. DOE will accept comments, data, and information regarding this rulemaking received no later than May 17, 2013.

ADDRESSES: Any comments submitted must identify the interim TSD for HID lamps and provide docket number EERE–2010–BT–STD–0043 and/or Regulation Identification Number (RIN) 1904–AC36, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.
- *Email: HIDLamps-2010-STD-0043@ee.doe.gov*. Include the docket number EERE–2010–BT–STD–0043 and/or RIN 1904–AC36 in the subject line of the message.
- *Mail:* Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Program, Mailstop EE–2J, 1000 Independence Avenue SW., Washington, DC 20585–0121. If possible, please submit all items on a compact disc (CD), in which case it is not necessary to include printed copies. [Please note that comments and CDs sent by mail are often delayed and may be damaged by mail screening processes.]
- *Hand Delivery/Courier:* Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Program, 950 L'Enfant Plaza SW., Suite 600, Washington, DC 20024. Telephone (202) 586–2945. If possible, please submit all items on CD, in which case it is not necessary to include printed copies.

Docket: The docket is available for review at *www.regulations.gov*, including **Federal Register** notices, framework documents, public meeting attendee lists and transcripts, comments, and other supporting documents/materials. All documents in the docket are listed in the *www.regulations.gov* index. However, not all documents listed in the index may be publicly available, such as information that is exempt from public disclosure.

The rulemaking Web page can be found at: *http://www1.eere.energy.gov/buildings/appliance_standards/rulemaking.aspx/ruleid/23*. This Web page contains links to the interim technical support document and other supporting materials and information for this rulemaking on the regulations.gov site. The regulations.gov Web page contains instructions on how to access all documents in the docket, including public comments.

FOR FURTHER INFORMATION CONTACT: Ms. Lucy deButts, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies, EE–2J, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 287–1604. Email: *high_intensity_discharge_lamps@ee.doe.gov*.

In the Office of the General Counsel, contact Ms. Elizabeth Kohl, U.S. Department of Energy, Office of the General Counsel, GC–71, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 586–7796. Email: *elizabeth.kohl@hq.doe.gov*.

SUPPLEMENTARY INFORMATION: On February 28, 2013, the U.S. Department of Energy (DOE) published a notice of public meeting and availability of the interim analysis in the **Federal Register** (78 FR 13566) to make available and invite comments on the interim analysis for high-intensity discharge lamps energy conservation standards. The notice provided for the submission of comments by April 19, 2013, and comments will also be accepted at a public meeting to be held on April 2, 2013. The Appliance Standards Awareness Project (ASAP) and the National Electrical Manufacturers Association (NEMA) jointly requested a four-week extension of the comment period. ASAP and NEMA stated the additional time was needed for interested parties to consider and respond to the interim technical support document and public meeting presentation, and prepare and submit comments accordingly. DOE has determined that an extension of the public comment period is appropriate based on the foregoing reason and is hereby extending the comment period. DOE will consider any comments received by midnight of May 17, 2013, and deems any comments received by that time to be timely submitted.

Issued in Washington, DC, on April 1, 2013.

Kathleen B. Hogan,

Deputy Assistant Secretary for Energy Efficiency, Energy Efficiency and Renewable Energy.

[FR Doc. 2013–07971 Filed 4–4–13; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2013–0197; Directorate Identifier 2013–NE–09–AD]

RIN 2120–AA64

Airworthiness Directives; Pratt & Whitney Canada Corp. Turboprop Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain Pratt & Whitney Canada Corp. (P&WC) PW118A, PW118B, PW119B, PW119C, PW123, PW123B, PW123C, PW123D, PW123E, PW123AF, PW124B, PW125B, PW126A, PW127, PW127E, PW127F, PW127G, and PW127M turboprop engines. This proposed AD was prompted by reports of fractures of the 1st stage power turbine (PT) blade. This proposed AD would require inspection of the 1st stage PT blades and the removal from service of those blades that fail the inspection or their replacement with blades eligible for installation. We are proposing this AD to prevent fracture of the 1st stage PT blade, possible engine fire, and damage to the airplane.

DATES: We must receive comments on this proposed AD by June 4, 2013.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200

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

- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* 202–493–2251.

For service information identified in this AD, contact Pratt & Whitney Canada Corp., 1000 Marie-Victorin, Longueuil, Quebec, Canada, J4G 1A1; phone: 800–268–8000; fax: 450–647–2888; Web site: *www.pwc.ca.* You may view this service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

Examining the AD Docket

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

FOR FURTHER INFORMATION CONTACT: Frederick Zink, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7779; fax: 781–238–7199; email: *frederick.zink@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2013–0197; Directorate Identifier 2013–NE–09–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this proposed AD. Using the search function of the Web site, anyone can find and read the comments in any of our dockets, including, if provided, the name of the individual who sent the comment (or signed the comment on behalf of an association, business, labor union, etc.). You may review the DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

Discussion

Transport Canada, which is the aviation authority for Canada, has issued Canada Airworthiness Directive CF–2013–02, dated January 22, 2013, a Mandatory Continuing Airworthiness Information (referred to after this as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

> There have been various reported incidents of P&WC PW100 series engine failures caused by the fracturing of the 1st Stage Power turbine (PT1) blade. Some of the above cases have resulted in engine fires. Further investigation by P&WC has traced the affected PT1 blade failures to undetected shrinkage porosity of unacceptable levels within the blade casting. Service experience indicates that the blades manufactured between 2005 and 2008 exhibit a higher propensity for unacceptable levels of shrinkage porosity.

This proposed AD would require inspection of the blades for shrinkage porosity and replacement with blades eligible for installation for those blades that fail the inspection.

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

Relevant Service Information

P&WC has issued Alert Service Bulletin No. PW100–72–21823, Revision 3, dated March 8, 2013. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of Canada and is approved for operation in the United States. Pursuant to our bilateral agreement with Canada, they have notified us of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all information provided by Canada and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design. This proposed AD would require inspection of the 1st stage PT blades and the removal from service of those blades that fail the inspection or their replacement with blades eligible for installation.

Costs of Compliance

We estimate that this proposed AD would affect about 540 engines installed on U.S. airplanes. We also estimate that it would take about 1.5 hours per engine to perform the inspection or replacement required by this proposed AD. The average labor rate is $85 per hour. We estimate that 25% of the engines inspected would fail at least one 1st stage PT blade. If the 1st stage PT blade fails the inspection, a replacement blade would cost $6,000. Based on these figures, we estimate the cost of the inspection or replacement to U.S. operators to be $878,850.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

3. Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction; and

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Pratt & Whitney Canada Corp. (formerly Pratt & Whitney Canada Inc.): Docket No. FAA–2013–0197; Directorate Identifier 2013–NE–09–AD.

(a) Comments Due Date

We must receive comments by June 4, 2013.

(b) Affected Airworthiness Directives (ADs)

None.

(c) Applicability

This AD applies to Pratt & Whitney Canada Corp. (P&WC) PW118A, PW118B, PW119B, PW119C, PW123, PW123B, PW123C, PW123D, PW123E, PW123AF, PW124B, PW125B, PW126A, PW127, PW127E, PW127F, PW127G, and PW127M turboprop engines with a 1st stage power turbine (PT) blade part number (P/N) 3120973–01, P/N 3120983–01, or P/N 3054053–01 installed that has a serial number listed in Table 1 of the Appendix of P&WC Service Bulletin No. PW100–72–21823, Revision 3, dated March 8, 2013.

(d) Reason

This AD was prompted by reports of fractures of the 1st stage PT blade. We are issuing this AD to prevent fracture of the 1st stage PT blade, possible engine fire, and damage to the airplane.

(e) Actions and Compliance

Unless already done, within 60 months after the effective date of this AD or when the affected PT blades are at module level exposure, whichever occurs first, do one of the following:

(1) Replace the affected 1st stage PT blade with a blade eligible for installation; or

(2) Perform a one-time X-ray inspection of the affected 1st stage PT blades, using paragraph 3.F.(2) of the Accomplishment Instructions of P&WC Service Bulletin No. PW100–72–21823, Revision 3, dated March 8, 2013.

(f) Installation Prohibition

After the effective date of this AD, do not install into any engine any 1st stage PT blade that has not passed the inspection required by paragraph (e)(2) of this AD.

(g) Definition

For the purpose of this AD, module level exposure is when the affected engine is inducted into the engine shop, the PT module is removed from the engine, and access is available to the necessary subassembly.

(h) Credit for Previous Actions

If before the effective date of this AD, you inspected the 1st stage PT blades using earlier versions of P&WC Service Bulletin No. PW100–72–21823, Revision 3, dated March 8, 2013, you met the inspection requirements in paragraph (e) of this AD.

(i) Alternative Methods of Compliance (AMOCs)

The Manager, Engine Certification Office, FAA, may approve AMOCs to this AD. Use the procedures found in 14 CFR 39.19 to make your request.

(j) Related Information

(1) For more information about this AD, contact Frederick Zink, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7779; fax: 781–238–7199; email: *frederick.zink@faa.gov.*

(2) Refer to Transport Canada Airworthiness Directive CF–2013–02, dated January 22, 2013, and P&WC Service Bulletin No. PW100–72–21823, Revision 3, dated March 8, 2012, for related information.

(3) For service information identified in this AD, contact Pratt & Whitney Canada Corp., 1000 Marie-Victorin, Longueuil, Quebec, Canada, J4G 1A1; phone: (800) 268–8000; fax: 450–647–2888; Web site: *www.pwc.ca.* You may view this service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

Issued in Burlington, Massachusetts, on March 29, 2013.

Colleen M. D'Alessandro,

Assistant Manager, Engine & Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2013–07934 Filed 4–4–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2013–0143; Directorate Identifier 2013–NE–06–AD]

RIN 2120–AA64

Airworthiness Directives; Rolls-Royce plc Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain Rolls-Royce plc (RR) RB211–524B–02; –524B2–19; –524B3–02; –524B4–02; –524C2–19; –524D4–19; –524D4–B–19; –524D4–39; –535C–37; –535E4–37; –535E4–B–37, and –535E4–B–75 turbofan engines, and all RB211–524G2–19; –524G3–19; –524H2–19; and –524H–36 turbofan engines. This proposed AD was prompted by the discovery of a cracked and distorted front combustion liner (FCL) metering panel, which was made from the wrong material. This proposed AD would require a one-time inspection of the FCL metering panel to determine if it was made from N75 material and replacing it with one made from C263 material if it was made from N75 material. We are proposing this AD to prevent hot gas burning through the engine casing, which could result in an under-cowl fire and damage to the airplane.

DATES: We must receive comments on this proposed AD by June 4, 2013.

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

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

For service information identified in this proposed AD, contact Rolls-Royce plc, Corporate Communications, P.O. Box 31, Derby, England, DE248BJ; phone: 011–44–1332–242424; fax: 011–44–1332–249936 or email from *http://www.rolls-royce.com/contact/civil_team.jsp,* or download the publication from *https://*

www.aeromanager.com. You may view this service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

Examining the AD Docket

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

FOR FURTHER INFORMATION CONTACT:

Robert Green, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; email: *robert.green@faa.gov;* phone: 781–238–7754; fax: 781–238–7199.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2013–0143; Directorate Identifier 2013–NE–06–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this proposed AD. Using the search function of the Web site, anyone can find and read the comments in any of our dockets, including, if provided, the name of the individual who sent the comment (or signed the comment on behalf of an association, business, labor union, etc.). You may review the DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued mandatory continuing airworthiness information (MCAI) AD 2012–0215R1, dated January 4, 2013, to correct an unsafe condition for the specified products. The MCAI states:

> During investigation of a starting problem with an RB211–535E4–B–37 engine, the Fuel Spray Nozzles (FSNs) appeared misaligned and the engine was removed. Further investigation found that the FSNs were correctly positioned but that the Front Combustion Liner (FCL) metering panel (reference Engine Illustrated Parts Catalogue (EIPC) section 72–41–13, Figure/Item 02–324) was cracked and distorted. Laboratory investigation revealed that the FCL metering panel was made of N75 material rather than the specified C263 material.
>
> Rolls-Royce (RR) issued SB RB.211–72–7221 in 1984, to address the issue of cracking of FCL metering panels manufactured in N75 material. SB RB.211–72–7221 replaces the FCL metering panel manufactured in N75 material with one manufactured in C263 material. The FCL metering panel in so-called Phase 2 combustors of the RB211–524G/H and RB211–535C/E4/E4–B series engines was specified in C263 material from engine type at entry into service.
>
> Based on these findings, it was determined that installation of N75 material FCL metering panels on an engine where C263 was the intended material, may result in metering panel cracking and distortion.

This condition, if not prevented, could result in hot gas burning through the engine casing, which could result in an under-cowl fire and damage to the airplane. You may obtain further information by examining the MCAI in the AD docket.

Relevant Service Information

RR Alert Non-Modification Service Bulletin (NMSB) No. RB.211–72–AG046, Revision 3, dated December 6, 2012, and Alert NMSB No. RB.211–72–AG183, Revision 3, dated December 6, 2012.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of the United Kingdom, and is approved for operation in the United States. Pursuant to our bilateral agreement with the European Community, EASA has notified us of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all information provided by EASA and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design. This proposed AD would require a one-time inspection of the FCL metering panel to determine if it was made from N75 material, and replacing it with one made from C263 material if it was made from N75 material.

Costs of Compliance

We estimate that this proposed AD would affect 315 RR turbofan engines installed on airplanes of U.S. registry. We also estimate that it would take about 11 hours per engine to inspect the FCL metering panel on-wing. The average labor rate is $85 per hour. Required parts cost about $108,887 per engine. We anticipate that 12 FCL metering panels will fail inspection. Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be $1,601,169.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

(3) Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction, and

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Rolls-Royce plc: Docket No. FAA–2013–0143; Directorate Identifier 2013–NE–06–AD.

(a) Comments Due Date

We must receive comments by June 4, 2013.

(b) Affected Airworthiness Directives (ADs)

None.

(c) Applicability

This AD applies to:

(1) All Rolls-Royce plc (RR) RB211–524G2–19; –524G3–19; –524H2–19; and –524H–36 turbofan engines.

(2) RR RB211–524B–02; –524B2–19; –524B3–02; –524B4–02; –524C2–19; –524D4–19; –524D4–B–19; and –524D4–39 that have incorporated RR Service Bulletin (SB) No. RB.211–72–7221, dated December 7, 1984.

(3) All RR RB211–535C–37; –535E4–37; –535E4–B–37, and –535E4–B–75 turbofan engines, except those engines that have incorporated RR SB No. RB.211–72–C230, dated November 16, 1999, or Revision 1, dated November 22, 2012.

(4) This AD does not apply to engines listed in paragraphs (c)(1) through (c)(3):

(i) That have installed a front combustion liner (FCL) metering panel delivered from RR after April 23, 2011; or

(ii) That were inspected before the effective date of this AD using RR Alert Non-Modification Service Bulletin (NMSB) No. RB.211–72–AF572, dated October 15, 2007, or Revision 1, dated October 8, 2008, or Revision 2, dated April 2, 2009, or RR Repeater Technical Variance No. 75295, Issue 1, dated April 20, 2007.

(d) Reason

This AD was prompted by the discovery of a cracked and distorted FCL metering panel, made from the wrong material. We are issuing this AD to prevent hot gas burning through the engine casing, which could result in an under-cowl fire and damage to the airplane.

(e) Actions and Compliance

Unless already done, do the following actions.

(1) At the next engine shop visit or within 625 flight cycles, whichever occurs first after the effective date of this AD, perform a one-time inspection of the FCL metering panel to determine if it was made from N75 material, and replace it if made from N75 material, with one made from C263 material.

(2) To inspect RB211–524 series turbofan engines, use Section 3., Accomplishment Instructions, of Alert NMSB No. RB.211–72–AG183, Revision 3, dated December 6, 2012, except reporting requirement paragraph 2 of Appendices 1 and 2 of that Alert NMSB.

(3) To inspect RB211–535 series turbofan engines, use Section 3., Accomplishment Instructions, of Alert NMSB No. RB.211–72–AG046, Revision 3, dated December 6, 2012, except reporting requirement paragraph 2 of Appendices 1 and 2 of that Alert NMSB.

(f) Definitions

For the purpose of this AD, a shop visit is the induction of an engine into the shop for maintenance or overhaul. The separation of engine flanges solely for the purposes of transporting the engine without subsequent engine maintenance does not constitute an engine shop visit.

(g) Alternative Methods of Compliance (AMOCs)

The Manager, Engine Certification Office, may approve AMOCs for this AD. Use the procedures found in 14 CFR 39.19 to make your request.

(h) Related Information

(1) For more information about this AD, contact Robert Green, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; email: *robert.green@faa.gov*; phone: 781–238–7754; fax: 781–238 7199.

(2) Refer to European Aviation Safety Agency AD 2012–0215R1, dated January 4, 2013, RR Alert NMSB No. RB.211–72–AG183, Revision 3, dated December 6, 2012, and Alert NMSB No. RB.211–72–AG046, Revision 3, dated December 6, 2012, for related information.

(3) For service information identified in this AD, contact Rolls-Royce plc, Corporate Communications, P.O. Box 31, Derby, England, DE248BJ; phone: 011–44–1332–242424; fax: 011–44–1332–249936 or email from *http://www.rolls-royce.com/contact/civil_team.jsp,* or download the publication from *https://www.aeromanager.com.* You may view this service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

Issued in Burlington, Massachusetts, on March 29, 2013.

Colleen M. D'Alessandro,

Assistant Manager, Engine & Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2013–07930 Filed 4–4–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2013–0052; Directorate Identifier 2013–NE–02–AD]

RIN 2120–AA64

Airworthiness Directives; Rolls-Royce plc Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for all Rolls-Royce plc (RR) RB211–535E4–37, RB211–535E4–B–37, RB211–535E4–C–37, and RB211–535E4–B–75 turbofan engines. This proposed AD was prompted by RR updating the low-cycle-fatigue life analysis for the low pressure turbine (LPT) stage 2 discs. This proposed AD would require removal of affected parts using a drawdown plan. We are proposing this AD to prevent LPT stage 2 disc failure, which could result in uncontained engine damage and damage to the airplane.

DATES: We must receive comments on this proposed AD by June 4, 2013.

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

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

For service information identified in this AD, contact Rolls-Royce plc, Corporate Communications, P.O. Box 31, Derby, England, DE248BJ; phone: 011–44–1332–242424; fax: 011–44–1332–249936; or email from *http://www.rolls-royce.com/contact/civil_team.jsp;* or download the publication from *https://*

www.aeromanager.com. You may view this service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803. For information on the availability of this material at the FAA, call 781–238–7125.

Examining the AD Docket

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

FOR FURTHER INFORMATION CONTACT:

Robert Green, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7754; fax: 781–238–7199; email: *Robert.Green@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2013–0052; Directorate Identifier 2013–NE–02–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this proposed AD. Using the search function of the Web site, anyone can find and read the comments in any of our dockets, including, if provided, the name of the individual who sent the comment (or signed the comment on behalf of an association, business, labor union, etc.). You may review the DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA AD 2012–0266, dated December 18, 2012, to correct an unsafe condition for the specified products. That mandatory continuing airworthiness information (MCAI) states:

> A recent re-evaluation of Critical Part lives carried out by Rolls-Royce revealed changes to the thermal profile and stresses in certain features of the low pressure turbine (LPT) Stage 2 disc. These changes have resulted in a reduction of the cyclic life of the LPT stage 2 discs.
>
> Operation of an engine equipped with a Critical Part that has exceeded its cyclic life may result in Critical Part failure, consequent release of high energy debris, damage to the aeroplane and/or injury to occupants.

We are proposing this AD to prevent LPT stage 2 disc failure, which could result in uncontained engine damage and damage to the airplane. You may obtain further information by examining the MCAI in the AD docket.

Relevant Service Information

RR has issued Alert Non-Modification Service Bulletin (NMSB) No. RB.211–72–AH029, dated December 13, 2012. The NMSB introduces new LPT stage 2 disc part lives that will be the drawdown plan retirement thresholds.

FAA's Determination and Requirements of this Proposed AD

This product has been approved by the aviation authority of the United Kingdom and is approved for operation in the United States. Pursuant to our bilateral agreement with the European Community, EASA has notified us of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all information provided by EASA and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design. This proposed AD would require removal of affected LPT stage 2 discs using a drawdown plan.

Differences Between the AD and the MCAI or Service Information

This AD differs from EASA AD 2012–0266, dated December 18, 2012, as follows: The EASA AD specifies replacing the affected critical parts during the module disassembly if the subsequent, anticipated time on wing (time before next shop visit) plus current life of the part will exceed the new provisional lives published in the RR Alert NMSB No. RB.211–72–AH029, dated December 13, 2012. We specify replacing at next shop visit (defined by the separation of a major flange).

Costs of Compliance

We estimate that this proposed AD would affect about 220 engines installed on airplanes of U.S. registry. The average labor rate is $85 per hour. We do not estimate any labor cost associated with this proposed AD because the affected parts are replaced during scheduled shop visits. Prorated cost of the parts adjusted for lost life is about $8,290 per engine. Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be $1,823,800.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

(1) Is not a ''significant regulatory action'' under Executive Order 12866;

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

(3) Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities

under the criteria of the Regulatory Flexibility Act.

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Rolls-Royce plc: Docket No. FAA–2013–0052; Directorate Identifier 2013–NE–02–AD.

(a) Comments Due Date

We must receive comments by June 4, 2013.

(b) Affected Airworthiness Directives (ADs)

None.

(c) Applicability

This AD applies to all Rolls-Royce plc (RR) RB211–535E4–37, RB211–535E4–B–37, RB211–535E4–C–37, and RB211–535E4–B–75 turbofan engines.

(d) Reason

This AD was prompted by RR updating the low-cycle-fatigue life analysis for the low pressure turbine (LPT) stage 2 discs. We are issuing this AD to prevent LPT stage 2 disc failure, which could result in uncontained engine damage and damage to the airplane.

(e) Actions and Compliance

(1) Within 30 days after the effective date of this AD, re-calculate the cyclic life since new of each LPT stage 2 disc. Use the part lives and prorated life formulas in Appendices 1, 2, and 3 of RR Alert Non-Modification Service Bulletin (NMSB) No. RB.211–72–AH029, dated December 13, 2012, to make that calculation.

(2) Assign the Maximum Approved Lives defined in Appendix 1 of Alert NMSB No. RB.211–72–AH029, dated December 13, 2012, to the LPT stage 2 disc based on the flight profile that will be flown.

(3) For engines that have an engine shop visit (ESV) after the effective date of this AD, remove the LPT stage 2 disc from service before the part exceeds the maximum approved life assigned in paragraph (e)(2) of this AD.

(4) For those engines that do not have an ESV after the effective date of this AD before the part exceeds the part life assigned in paragraph (e)(2) of this AD, remove the part from service at the next ESV.

(f) Installation Prohibition

With the exception of parts that can be reworked using RR Service Bulletin No. RB.211–72–D365, Revision 5, dated December 13, 2012, do not reinstall any part removed per this AD into any engine.

(g) Definitions

For the purpose of this AD, an ESV is whenever engine maintenance performed prior to reinstallation requires the separation of a pair of major mating engine module flanges. Separation of flanges solely for the purpose of shipment without subsequent internal maintenance is not a shop visit.

(h) Alternative Methods of Compliance (AMOCs)

The Manager, Engine Certification Office, FAA, may approve AMOCs to this AD. Use the procedures found in 14 CFR 39.19 to make your request.

(i) Related Information

(1) For more information about this AD, contact Robert Green, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7754; fax: 781–238–7199; email: *Robert.Green@faa.gov*.

(2) Refer to European Aviation Safety Agency Airworthiness Directive 2012–0266, dated December 18, 2012, and RR Alert NMSB No. RB.211–72–AH029, dated December 13, 2012, for related information.

(3) For service information identified in this AD, contact Rolls-Royce plc, Corporate Communications, P.O. Box 31, Derby, England, DE248BJ; phone: 011–44–1332–242424; fax: 011–44–1332–249936; or email from *http://www.rolls-royce.com/contact/civil_team.jsp;* or download the publication from *https://www.aeromanager.com*. You may view this service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803. For information on the availability of this material at the FAA, call 781–238–7125.

Issued in Burlington, Massachusetts, on March 28, 2013.

Colleen M. D'Alessandro,

Assistant Manager, Engine & Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2013–07931 Filed 4–4–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2013–0029; Directorate Identifier 2013–NE–01–AD]

RIN 2120–AA64

Airworthiness Directives; Rolls-Royce plc Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for all Rolls-Royce plc (RR) RB211–535E4–B–37 series turbofan engines. This proposed AD was prompted by recalculating the life of certain life limited parts operated to certain flight profiles. This proposed AD would require removal of affected parts using a drawdown plan. We are proposing this AD to prevent the failure of critical rotating parts, which could result in uncontained failure of the engine and damage to the airplane.

DATES: We must receive comments on this proposed AD by June 4, 2013.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

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

For service information identified in this proposed AD, contact Rolls-Royce plc, Corporate Communications, P.O. Box 31, Derby, England, DE248BJ; phone: 011–44–1332–242424; fax: 011–44–1332–249936 or email from *http://www.rolls-royce.com/contact/civil_team.jsp,* or download the publication from *https://www.aeromanager.com*. You may view this service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

Examining the AD Docket

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

FOR FURTHER INFORMATION CONTACT: Robert Green, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; email: *robert.green@faa.gov;* phone: 781–238–7754; fax: 781–238–7199.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2013–0029; Directorate Identifier 2013–NE–01–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

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

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA AD 2012–0265, dated December 18, 2012 (referred to herein after as ''the MCAI''), to correct an unsafe condition for the specified product. The MCAI states:

> Flight Profiles (FP) define the limits of engine operation within which the engine will qualify for use of an associated set of Critical Parts life limits. The Rolls-Royce RB211–535E4–B–37 engine previously had only one such FP and associated set of life limits published in the applicable RR Time Limits Manual.
>
> However, a recent review of operational flight data has revealed that some engines may have been operated beyond the currently valid datum FP.
>
> Failure to account for the correct rate of fatigue damage associated with engine operation may lead to Critical Parts failure, possibly resulting in release of high energy debris, damage to the aeroplane and/or injury to occupants.

We are proposing this AD to prevent the failure of critical rotating parts, which could result in uncontained failure of the engine and damage to the airplane. You may obtain further information by examining the MCAI in the AD docket.

Relevant Service Information

RR has issued Alert Non-Modification Service Bulletin (NMSB) No. RB.211–72–AG875, dated December 13, 2012. The Alert NMSB introduces two new datum flight profiles (Flight Profile D and Flight Profile E) and the life-limited part lives that are the drawdown plan retirement thresholds.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of the United Kingdom, and is approved for operation in the United States. Pursuant to our bilateral agreement with the European Community, EASA has notified us of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all information provided by EASA and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design. This proposed AD would require removal of affected parts using a drawdown plan.

Differences Between the AD and the MCAI or Service Information

This AD differs from EASA AD 2012–0265, dated December 18, 2012, as follows: The EASA AD specifies replacing the affected critical parts during the module disassembly if the subsequent, anticipated time on wing (time before next shop visit) plus current life of the part will exceed the new provisional lives published in the RR Alert NMSB. We specify replacing at next shop visit (defined by the separation of a major flange).

Costs of Compliance

We estimate that this proposed AD would affect about 377 engines installed on airplanes of U.S. registry. Of these 377 engines, we estimate 95 engines operate to Flight Profile D or E. The average labor rate is $85 per work hour. We do not estimate any labor cost is associated with this proposed AD because the affected parts are replaced at the next shop visit. Prorated cost of parts adjusted to Flight Profile D operation, would cost about $77,672 per engine. Prorated cost of parts adjusted to Flight Profile E operation, would cost about $204,981 per engine. Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be $11,834,655.

Authority for this Rulemaking

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

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

Regulatory Findings

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

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

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

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

(3) Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction, and

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Rolls-Royce plc: Docket No. FAA–2013–0029; Directorate Identifier 2013–NE–01–AD.

(a) Comments Due Date

We must receive comments by June 4, 2013.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Rolls-Royce plc (RR) RB211–535E4–B–37 series turbofan engines.

(d) Unsafe Condition

This AD was prompted by recalculating the life of certain life limited parts operated to certain flight profiles. We are issuing this AD to prevent the failure of critical rotating parts, which could result in uncontained failure of the engine and damage to the airplane.

(e) Compliance

Comply with this AD within the compliance times specified, unless already done.

(1) Within 30 days after the effective date of this AD for engines that have operated to Flight Profile D or E, recalculate the life of the low-pressure (LP) turbine disc stage 2, intermediate-pressure (IP) compressor rotor shaft (stage 1 to 6), high-pressure (HP) compressor rear rotor shaft assembly, and HP turbine disc installed on that engine. Use the part lives, prorated life formulas, and flight profiles in Appendices 2, 4, and 5 of RR Alert Non-Modification Service Bulletin (NMSB) No. RB.211–72–AG875, dated December 13, 2012, to make that calculation.

(2) Within 30 days after the effective date of this AD for engines that will operate to Flight Profile D or E, assign the Maximum Approved Lives defined in Appendix 2 of RR Alert NMSB No. RB.211–72–AG875, dated December 13, 2012, to the LP turbine disc Stage 2, IP compressor rotor shaft (stage 1 to 6), HP compressor rear rotor shaft assembly, and HP turbine disc based on the flight profile that will be flown.

(3) For engines that have only operated to, and will continue to operate to, Flight Profile C, as defined in Appendix 5 of RR Alert NMSB No. RB.211–72–AG875, dated December 13, 2012, no further action is required by this AD.

(4) For engines that incorporate an LP turbine disc stage 2, IP compressor rotor shaft (stage 1 to 6), HP compressor rear rotor shaft assembly, or HP turbine disc whose part life is defined by paragraph (e)(1) of this AD that have an engine shop visit (ESV) after the effective date of this AD, remove each part from service before the part exceeds the part life assigned in paragraph (e)(2) of this AD.

(5) For those engines that incorporate an LP turbine disc stage 2, IP compressor rotor shaft (stage 1 to 6), HP compressor rear rotor shaft assembly, or HP turbine disc whose part life is defined by paragraph (e)(1) of this AD, that do not have an ESV after the effective date of this AD before the part exceeds the part life assigned in paragraph (e)(2) of this AD, remove the part from service at the next ESV.

(f) Installation Prohibition

After the effective date of this AD, any LP turbine disc stage 2, IP compressor rotor shaft (stage 1 to 6), HP compressor rear rotor shaft assembly, or HP turbine disc whose part life is defined by paragraph (e)(1) of this AD that is re-installed in any engine after the effective date of this AD must be removed from service before the part exceeds the part life assigned in paragraph (e)(2) of this AD.

(g) Definitions

For the purpose of this AD, ESV is whenever engine maintenance performed prior to reinstallation requires the separation of a pair of major mating engine module flanges. Separation of flanges solely for the purpose of shipment without subsequent internal maintenance, is not an ESV.

(h) Alternative Methods of Compliance (AMOCs)

The Manager, Engine Certification Office, may approve AMOCs for this AD. Use the procedures found in 14 CFR 39.19 to make your request.

(i) Related Information

(1) For more information about this AD, contact Robert Green, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; email: *robert.green@faa.gov;* phone: 781–238–7754; fax: 781–238–7199.

(2) Refer to EASA AD 2012–0265, dated December 18, 2012, for related information.

(3) For service information identified in this AD, contact Rolls-Royce plc, Corporate Communications, P.O. Box 31, Derby, England, DE248BJ; phone: 011–44–1332–242424; fax: 011–44–1332–249936 or email from *http://www.rolls-royce.com/contact/civil_team.jsp,* or download the publication from *https://www.aeromanager.com.* You may view this service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

Issued in Burlington, Massachusetts, on March 29, 2013.

Colleen M. D'Alessandro,

Assistant Manager, Engine & Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2013–07935 Filed 4–4–13; 8:45 am]

BILLING CODE 4910–13–P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1112 and 1226

[Docket No. CPSC–2013–0014]

Safety Standard for Soft Infant and Toddler Carriers

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Danny Keysar Child Product Safety Notification Act, Section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), requires the United States Consumer Product Safety Commission (Commission or CPSC) to promulgate consumer product safety standards for durable infant or toddler products. These standards are to be ''substantially the same as'' applicable voluntary standards or more stringent than the voluntary standard if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the product. The Commission is proposing a safety standard for soft infant and toddler carriers in response to the direction under Section 104(b) of the CPSIA.[1]

DATES: Submit comments by June 19, 2013.

ADDRESSES: Comments related to the Paperwork Reduction Act aspects of the marking, labeling, and instructional literature of the proposed rule should be directed to the Office of Information and Regulatory Affairs, OMB, Attn: CPSC Desk Officer, FAX: 202–395–6974, or emailed to *oira_submission@omb.eop.gov.*

Other comments, identified by Docket No. CPSC–2013–0014, may be submitted electronically or in writing:

[1] The Commission voted 2–1 to approve publication of this proposed rule. Chairman Inez M. Tenenbaum and Commissioner Robert S. Adler voted to approve publication, and Commissioner Nancy A. Nord voted against publication. Commissioner's statements concerning this or any other Commission action may be viewed by clicking on a specific Commissioner's name and selecting ''Statements'' on the Commission's Web site at *http://www.cpsc.gov/en/About-CPSC/Commissioners/,* or obtained from the Commission's Office of the Secretary.

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: *http://www.regulations.gov*. Follow the instructions for submitting comments. The Commission does not accept comments submitted by electronic mail (email), except through *www.regulations.gov*. The Commission encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

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

Instructions: All submissions received must include the agency name and docket number for this proposed rulemaking. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to: *http://www.regulations.gov*. Do not submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If furnished at all, such information should be submitted in writing.

Docket: For access to the docket to read background documents or comments received, go to: *http://www.regulations.gov,* and insert the docket number, CPSC–2013–0014, into the ''Search'' box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Gregory K. Rea, Project Manager, Director, Division of Mechanical Engineering, Directorate for Laboratory Sciences, Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; telephone: 301–987–2258; email: *grea@cpsc.gov*.

SUPPLEMENTARY INFORMATION:

I. Background and Statutory Authority

The Consumer Product Safety Improvement Act of 2008 (CPSIA, Pub Law 110–314) was enacted on August 14, 2008. Section 104(b) of the CPSIA, part of the Danny Keysar Child Product Safety Notification Act, requires the Commission to: (1) Examine and assess the effectiveness of voluntary consumer product safety standards for durable infant or toddler products, in consultation with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts; and (2) promulgate consumer product safety standards for durable infant and toddler products. These standards are to be ''substantially the same as'' applicable voluntary standards or more stringent than the voluntary standard if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the product. The term ''durable infant or toddler product'' is defined in section 104(f)(1) of the CPSIA as ''a durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years.''

In this document, the Commission is proposing a safety standard for soft infant and toddler carriers. ''Infant carriers'' are specifically identified in section 104(f)(2)(H) of the CPSIA as durable infant or toddler products. The Commission has identified at least four types of products that fall within the product category of ''infant carriers,'' including: Frame backpack carriers, handheld infant carriers, slings, and soft infant and toddler carriers. This proposed rule addresses hazards associated only with soft infant and toddler carriers. Recently, the Commission issued a proposed rule on handheld infant carriers (77 FR 73354 (Dec. 10, 2012)). Hazards associated with frame backpack carriers and slings will be addressed separately in future rulemaking proceedings.

Pursuant to Section 104(b)(1)(A), the Commission consulted with manufacturers, retailers, trade organizations, laboratories, consumer advocacy groups, consultants, and members of the public in the development of this proposed standard, largely through the ASTM process. The proposed rule is based on the voluntary standard developed by ASTM International (formerly the American Society for Testing and Materials), ASTM F2236–13, ''Standard Consumer Safety Specification for Soft Infant and Toddler Carriers'' (ASTM F2236–13), without alteration. The ASTM standard is copyrighted, but it can be viewed as a read-only document during the comment period on this proposal only, at: *http://www.astm.org/cpsc.htm,* by permission of ASTM.

II. Product Description

A. Definition of a Soft Infant and Toddler Carrier

ASTM F2236–13 defines ''soft infant and toddler carrier'' as ''a product, normally of sewn fabric construction, which is designed to contain a full term infant to a toddler, generally in an upright position, in close proximity to the caregiver.'' Additionally, soft infant and toddler carriers are generally designed to carry a child ''between 7 and 45 pounds.'' ASTM F2236–13 explains that soft infant and toddler carriers are ''normally 'worn' by the caregiver with a child positioned in the carrier and the weight of the child and carrier suspended from one or both shoulders of the caregiver. These products may be worn on the front, side, or back of the caregiver's body, with the infant either facing towards or away from the caregiver.'' Typically children are carried in soft infant and toddler carriers on the front of a caregiver, but some products on the market can be configured to carry a child upright on a caregiver's front, back, or hip.

Two broad classes of soft infant and toddler carriers are available in the United States: Structured and nonstructured. Structured soft infant and toddler carriers contain straps and waist belts that connect, to the seat area of the carrier and each other, with buckles, straps, and other mechanical fasteners. The straps, belts, and seating area of these products are often stiffened with padding and typically have a heavy textile covering. Nonstructured products, such as the mei-tai design, consist of a flat, textile center that acts as the seat area with waist straps and very long (5 to 6 feet) upper straps. The upper straps wrap over the caregiver's shoulders, cross in the back, and are brought around the waist to the front of the caregiver. The upper straps are then secured over the child's legs to form the leg openings and secure the child in an upright position. ASTM F2236–13 does not distinguish between products based on whether they are structured or nonstructured; requirements apply equally to all types of soft infant and toddler carriers.

The definition of a ''soft infant and toddler carrier'' is intended to distinguish it from other types of infant carriers that are also worn by a caregiver but that are not covered under ASTM F–2236–13, specifically slings (including wraps), and framed backpack carriers. Soft infant and toddler carriers are designed to carry a child in an upright position. Slings are designed to carry a child in a reclined position; although some slings may also be used to carry a child upright. Thus, the primary distinction between a sling and a soft infant and toddler carrier is the sling's design that allows for carrying a child in a reclined position. Different hazard patterns arise from carrying a child in a reclined position. Accordingly, slings are not included in the standard for soft infant and toddler carriers. Like soft infant and toddler carriers, framed backpack carriers are intended to carry

a child in an upright position, but are distinguishable because typically, they are constructed of sewn fabric over a rigid metal structure and are solely intended for carrying a child on the caregiver's back.

B. Market Description

Soft infant and toddler carriers are generally produced and/or marketed by juvenile product manufacturers and distributors. Several of these firms focus exclusively on soft infant and toddler carriers, as well as substitute products, such as slings. CPSC staff believes that at least 39 firms supply soft infant and toddler carriers to the U.S. market. Thirty-one domestic firms supply soft infant and toddler carriers to the U.S. market: 15 are domestic manufacturers; eight are domestic importers; and the supply sources of eight domestic firms are unknown. Five foreign firms supply soft infant and toddler carriers to the U.S. market: three are foreign manufacturers; one is a foreign importer; and one firm has an unknown supply source. Insufficient information is available on the remaining three firms to categorize them.

According to a 2005 survey conducted by the American Baby Group (*2006 Baby Products Tracking Study*), 51 percent of new mothers own soft infant and toddler carriers. Approximately 30 percent of soft infant and toddler carriers were handed down or purchased secondhand, meaning that about 70 percent of the products were acquired new. This suggests that approximately 1.5 million soft infant and toddler carriers are sold to households annually ($.51 \times .70 \times 4.1$ million births per year). Typically, soft infant and toddler carriers are used during a child's first year, with some caregivers continuing to use these products into the second year. We estimate use into a child's second year under the assumption that approximately 25–50 percent of caregivers continue to use these products. Based on data from the *2006 Baby Products Tracking Study,* approximately 2.1 million soft infant and toddler carriers are owned by new mothers. Thus, we estimate that approximately 2.6–3.2 million households have soft infant and toddler carriers available for use annually.

III. Incident Data

CPSC's Directorate for Epidemiology, Division of Hazard Analysis is aware of 93 incidents related to soft infant and toddler carriers—reported over a period of nearly 13 years—beginning in January 1999 through early September 2012. Two incidents involved a fatality, and 91 incidents were nonfatal.

A. Fatalities

Two suffocation fatalities were reported to CPSC from January 1999 to September 2012. The first fatality involved a 5-week-old male who fell asleep in the soft infant and toddler carrier after a feeding. About 20 minutes after the feeding, he appeared unresponsive. The official cause of death was listed as positional asphyxia. The second fatal incident occurred when a 2-month-old female fell asleep in a soft infant and toddler carrier worn by her parent. The parent lay down on a couch to sleep for the night while still wearing the carrier with the infant inside. The parent awoke the next morning to find the child unresponsive with her face pressed into the parent's chest. Staff could not directly attribute the two reported fatalities to product design or mechanical failure of the soft infant and toddler carrier.

B. Nonfatalities

Approximately 33 percent (30) of the 91 nonfatal incidents involved reports of an injury to an infant during use of a soft infant and toddler carrier. A majority of the injuries resulted from falls from the carrier. All of the injuries in which the age of the victim was available were reportedly sustained by infants who were 1 month to 13 months old. However, most of the incidents involved infants 6 months and younger. Although the remaining 61 nonfatal incidents reported that no injury had occurred, many of the descriptions indicated the potential for a serious injury or death.

Eight of the nonfatal incident reports involved skull fractures as a result of the childfalling out of the product. Five skull fracture injuries reportedly required hospitalization; the three remaining skull fracture injury reports did not mention any hospitalizations. Some of the remaining injuries reported included: Collarbone and limb fractures, contusions, abrasions, blisters, and scratches.

C. Hazard Pattern Identification

The primary hazard associated with use of a soft infant and toddler carrier is falling, either caregivers falling while wearing the carrier and injuring the child in the carrier, or children falling or facing the risk of falling from the carrier due to fastener problems, large leg openings, stitching or seam problems, or straps that slip. A majority of the reported incidents summarized in Table 1 below, and all seven of the recalls described in section III.E, involved an actual fall or potential risk of a child falling from a carrier.

Staff classified the 93 reported incidents by the issues—product feature, design element, or failure—primarily responsible for the incident and summarized this data in Table 1, below. An explanation of the categories represented in Table 1 follows.

Fastener problems: Twenty-five of the 93 incidents (27 percent) were related to fastener problems, such as snaps breaking/unexpectedly releasing, or buckles breaking/detaching/pinching/unexpectedly releasing. Six injuries, but no fatalities, were included among these reports.

Structure, fit, and position issues: Fourteen of the 93 incidents (15 percent) were related to aspects of the leg- and torso-opening design, how the carrier held the infant, and where the carrier was positioned on the caregiver. Examples of scenarios reported include: An infant slipping down far into the carrier and suffering an injury when the caregiver went into a bent position; an infant falling out of the carrier when the caregiver bent forward; and leg circulation-related injuries. There were 10 injuries reported in this category. No reported fatalities were associated with this issue.

Problems with large leg openings: Twelve of the 93 incidents (13 percent) were related to leg openings that were too large and that allowed the infant to slip through completely and fall out of the carrier. While there were no fatalities among these reports, there were seven injuries; three involved infants who were hospitalized for skull fractures.

Issues with stitching/seams: Ten reports (11 percent) were received about stitching on the carrier coming undone or seams ripping, resulting in other components, like straps, detaching and creating a fall hazard. One injury was included among these reports.

Design and finish-related issues: Eight reports (nine percent) of inadequate back support, rough fabric, poor air flow in the carrier insert, and other design issues were received. No fatalities were noted, but two injuries were associated with these issues.

Strap issues: Eight incidents (nine percent) reported issues with straps, mostly about the adjuster breaking or slipping. No injuries or fatalities were reported in this category.

Other issues: Eleven reports (12 percent) were related to issues other than those described above. Two fatalities and four injuries, including two hospitalizations, were reported in this category. The two fatalities—one case of a parent falling asleep while

wearing the carrier with the infant inside, and the other case of an infant suffering respiratory distress while being carried around facing in—are included in this category. In each case, CPSC staff concluded that there were too many confounding factors reported to determine that a specific factor contributed predominantly to the deaths. The remaining reports were of unspecified falls, an nonspecific abrasion injury, and an incidental injury to the infant, due to a caregiver's fall.

TABLE 1—DISTRIBUTION OF REPORTED INCIDENTS BY HAZARD PATTERNS ASSOCIATED WITH SOFT INFANT AND TODDLER CARRIERS REPORTING PERIOD: JANUARY 1, 1999–SEPTEMBER 10, 2012

Issues	Total reports		Deaths		Injuries	
	Count	Percentage	Count	Percentage	Count	Percentage
Mechanical Issues	77	83	0	0	26	87
Fasteners	*25*	*27*	*0*	*0*	*6*	*20*
Structure, fit, and position	*14*	*15*	*0*	*0*	*10*	*33*
Large leg openings	*12*	*13*	*0*	*0*	[1] *7*	*23*
Stitching/seams	*10*	*11*	*0*	*0*	*1*	*3*
Design and finish	*8*	*9*	*0*	*0*	*2*	*7*
Straps	*8*	*9*	*0*	*0*	*0*	*0*
Other	11	12	2	100	[2] 4	13
Consumer Comments	5	5	0	0	0	0
Total	93	100	2	100	30	100

Source: U.S. Consumer Product Safety Commission's epidemiological databases IPII, INDP, and DTHS.
Note: The percentages have been rounded to the 2nearest integer. Subtotals do not necessarily add to heading totals.
[1] (3 hosp.).
[2] (2 hosp.).

D. NEISS Data

In addition to the 93 incident reports received by the Commission, we estimated the number of injuries treated in U.S. hospital emergency departments using the CPSC's National Electronic Injury Surveillance System (NEISS). We estimate that over a 13-year-period, a total of 1,400 injuries related to soft infant and toddler carriers were treated in U.S. hospital emergency departments from 1999 through 2011. Because CPSC's NEISS data for 2012 will be finalized in spring 2013, partial estimates for 2012 are not available. The injury estimates for individual years are based on very small samples and are not reportable. According to the NEISS publication criteria, an estimate must be 1,200 or greater, the sample size must be 20 or greater, and the coefficient of variation must be 33 percent or smaller. Moreover, due to the unreliability of the yearly estimates, a trend analysis is not feasible.

No fatalities were reported through NEISS. Although data extraction criteria included ages up to 4 years, all of the injured children were reported to be less than 2 years of age. A breakdown of the characteristics among the emergency department-treated injuries associated with soft infant and toddler carriers is presented in the bullets below.

- Hazard—Getting struck while in the carrier when caregiver fell (65%); falling out of the carrier (21%).
- Injured body part—Head (63%); face (11%).
- Injury type—Internal organ injury (48%); contusions/abrasions (19%); and fractures (12%).
- Disposition—Treated and released (79%); hospitalized (10%); and treated and transferred (9%).

E. Product Recalls

Seven product safety recalls, recalling 652,250 units, were announced between January 1, 1999 and June 17, 2010 that involved a fall hazard related to use of a soft infant and toddler carrier. These recalls related to 130 incident reports received by the CPSC. A breakdown of the specific product defect necessitating the recall, product units involved, and the number of incident reports received is presented in the chart below. At the time the products were recalled, nine infants had been injured significantly in incidents that ranged from bruises to skull fractures. Additional information on these recalls can be found on the Commission's Web sites at: *www.cpsc.gov* or *www.saferproducts.gov.*

SOFT INFANT AND TODDLER CARRIER RECALL SUMMARY

[January 1, 1999 through June 17, 2010]

Manufacturer	Model	Year recalled	Units recalled	Reason	Incident reports	Injury reports
Evenflo Company & Hufco-Delaware, Inc..	Model 070 & 080 Snugli® Front and Back Pack™.	1999	327,000	Infant shifts to side & slips through leg opening, falls out.	13	One—fractured skull; two—bruises.
Baby Swede, LLC	Baby Bjorn	1999	240,000 (Recall to Repair).	Infants slip through leg openings—fall. Infants < 2 months—highest risk.	9	Six fractured skulls.
Baby Swede, LLC	Baby Bjorn Carrier Active.	2004	49,000	Back support buckles detach from shoulder straps—pose fall hazard.	93	No injuries reported.

SOFT INFANT AND TODDLER CARRIER RECALL SUMMARY—Continued

[January 1, 1999 through June 17, 2010]

Manufacturer	Model	Year recalled	Units recalled	Reason	Incident reports	Injury reports
Playtex Products, Inc	Playtex Hip Hammock	2005	32,000	Shoulder strap detaches from Hammock, posing fall hazard.	2	No injuries reported.
Beco Baby Carrier, Inc	Beco Baby Carrier Butterfly.	2008	2,000	Shoulder strap buckles unexpectedly release tension—straps slip through—pose fall hazard.	8	No injuries reported.
Optave, Inc	Action Baby Carrier	2008	250	Chest strap can detach from shoulder straps, posing fall hazard to infant.	2	No injuries reported.
Regal Lager, Inc	CYBEX 2. GO Infant Carriers.	2010	2,700 U.S. 400 Canada	Shoulder strap slider buckle can break, posing fall hazard to infant.	3	No injuries reported.

IV. Soft Infant and Toddler Carrier International Standard and ASTM Voluntary Standard

Section 104(b)(1)(A) of the CPSIA requires the Commission to consult representatives of ''consumer groups, juvenile product manufacturers, and independent child product engineers and experts'' to ''examine and assess the effectiveness of any voluntary consumer product safety standards for durable infant or toddler products.'' As a result of fall-related incidents and recalls of soft infant and toddler carriers, CPSC staff previously requested ASTM to develop voluntary requirements to address the hazards related to large leg openings. Through the ASTM process, we consulted with manufacturers, retailers, trade organizations, laboratories, consumer advocacy groups, consultants, and members of the public. The voluntary standard for soft infant carriers was first approved and published in April 2003, as ASTM F2236–03, *Standard Consumer Safety Performance Specification for Soft Infant Carriers.* It has been revised six times since then. The current version, ASTM F2236–13, renamed *Standard Consumer Safety Performance Specification for Soft Infant and Toddler Carriers,* was approved on March 1, 2013 and published in March 2013.

In addition to reviewing the ASTM standard, we reviewed the only international standard for soft infant carriers of which we are aware, EN13209–2:2005 *Child Use and Care Articles—Baby Carriers—Safety Requirements and Test Methods—Part 2: Soft Carrier.*

A. International Standard

CPSC evaluated requirements in ASTM F2236–13 and EN13209–2:2005 and determined that the requirements in ASTM F2236–13 are more stringent than EN13209–2:2005, and that they address the incidents seen in the data and reduce the risk of injury from these products. The few EN13209–2:2005 requirements without an ASTM F2236–13 counterpart address hazard patterns not found in the incident reports considered for this proposed rule.

B. Voluntary Standard—ASTM F2236

1. History of ASTM F2236

Initially, ASTM F2236–03 addressed falls related to large leg openings. The standard's bounded leg opening performance requirement limited the size of the leg opening to prevent infants from falling through large adjustable leg openings. The standard also established requirements to address sharp points and edges, small parts, lead in paints, wood parts, locking and latching of fasteners, dynamic load testing, static load testing, and product labeling. The scope of the standard was based on the manufacturers' recommended use of the product with infants weighing 7 to 25 pounds.

The next update of the voluntary standard was published in March 2008. ASTM F2236–03 addressed fall issues with bounded leg openings that were too large but did not consider the ability of an *unbounded* leg opening to retain the occupant. An unbounded leg opening is created by placing the soft carrier on a caregiver's torso, with a leg opening circumference comprised of carrier materials and the caregiver's torso. Accordingly, to address additional fall hazards, an unbounded leg opening performance requirement was added to ASTM F2236–08. ASTM F2236–08a was published in November 2008, to add general requirements included in other ASTM standards for durable children's products that address hazards associated with toy accessories and flammability.

ASTM F2236–09 was published in April 2009. The statement that the child occupant must face the caregiver until the child can hold its head upright was moved in this version of the standard from the warning label to be an informational statement. ASTM F2236–10, published in December 2010, clarified further that the informational statement for a child to face the caregiver until the child can hold its head upright was unnecessary for soft infant carriers that have only one use position with the child facing the caregiver.

ASTM F2236–12 was published in December 2012. Several sections of the voluntary standard were revised based on input from CPSC staff. The scope was expanded to increase the upper weight limit of products within the scope of the standard from 25 to 45 pounds and to include specifically in the title of the standard the word ''toddler.'' ASTM F2236–12 also included a new definition in the terminology section of the standard for ''carrying position,'' to clarify procedures for dynamic and static load testing. Finally, the test methods for dynamic Noand static load testing were modified to increase the weight load required for testing to ensure adequate testing of products that are designed to carry heavier children.

2. Description of the Current Voluntary Standard—ASTM F2236–13

ASTM F2236–13 was published in March 2013. Together with the changes described in ASTM F2236–12, ASTM F2236–13 reflects the most significant revisions to the standard, to date. Revisions include modified and new requirements developed by CPSC staff, working with stakeholders on the ASTM subcommittee task group, to address the hazards associated with soft infant and toddler carriers. ASTM F2236–13 includes the following key provisions: Scope, terminology, general requirements, performance requirements, test methods, marking and labeling, and instructional literature.

Scope. The scope of the standard was updated in December 2012, to broaden the upper weight limit from 25 to 45 pounds for products falling within the standard. Expanding the scope of the standard ensures that all soft infant and toddler carrier products currently on the market are covered by the standard. The name of the standard was altered at the same time to include the word ''toddler,'' to clarify that toddlers can also be carried in these products. The scope of the standard also distinguishes soft infant and toddler carriers from other wearable infant carrier products, by describing that soft infant and toddler carriers are ''normally of sewn fabric construction,'' hold the child ''generally in an upright position,'' and ''may be worn on the front, side, or back of the caregiver's body.'' Finally, the scope of the standard states that it does not apply to infant slings.

Terminology. Section 3.1 of the standard includes 14 definitions that help to explain general and performance requirements. Section 3.1.7 of the standard explains that a ''leg opening'' is the ''opening in the soft carrier through which the occupant's legs extend when the product is used in the manufacturer's recommended use position.'' Sections 3.1.4 and 3.1.13 of ASTM F2236–13, respectively, explain that a ''dynamic load'' is the ''application of impulsive force through free fall of a weight,'' and that a ''static load'' is a ''vertically downward force applied by a calibrated force gage or by dead weights.'' A new definition for ''carrying position'' was added in ASTM F2236–12, to clarify methods for dynamic and static load testing in section 7 of the standard. Also, a new definition for ''fastener'' was included in ASTM F2236–13, to aid in a new test for fastener strength and strap retention.

General Requirements. ASTM F2236–13 includes general requirements that the products must meet, as well as specified test methods to ensure compliance with the general requirements, which include:

- Restrictions on sharp points or edges, as defined by 16 CFR §§ 1500.48 and .49;
- Restrictions on small parts, as defined by 16 CFR part 1501;
- Restrictions on lead in paint, as set forth in 16 CFR part 1303;
- Requirements for locking and latching devices;
- Requirements for permanent warning labels;
- Restrictions on flammability, as set forth in 16 CFR part 1610;
- Requirements for toy accessories, as set forth in ASTM F 963.

The flammability requirement in section 5.7 of the standard was changed in ASTM F2236–13 from a flammable solids requirement (16 CFR 1500.3(c)(6)(vi)) to meet the more stringent flammability requirement for wearing apparel (16 CFR part 1610). The flammability requirement was altered to be consistent with other wearable infant carriers made of sewn fabric, such as slings, to prevent a foreseeable fire hazard in all wearable infant carriers.

Performance Requirements and Test Methods. ASTM F2236–13 provides performance requirements and test methods that are designed to protect against falls from the carrier due to large leg openings, breaking fasteners or seams, and straps that slip, including:

Leg Openings—Tested leg openings must not permit passage of a test sphere weighing 5 pounds that is 14.75 inches in circumference.

Dynamic and Static Load—Beginning with the 2012 version of ASTM F2236, the dynamic load test was strengthened from requiring a 25-lb. shot bag to be dropped, free fall, from 1 inch above the seat area onto the carrier seat 1,000 times, to requiring testing with a 25-lb, shot bag, or a shot bag equal to the manufacturer's maximum occupant weight limit, whichever is heavier. Also, the static load test was altered from requiring a 75-lb. weight for testing, to requiring a 75-lb. weight, or a weight equal to three times the manufacturer's recommended maximum occupant weight, whichever is greater, to be placed in the seat area of the carrier for 1 minute. This revision means that products with a maximum recommended weight of 45 pounds must be tested to a 135-pound weight instead of 75 pounds, an 80 percent increase in the severity of the requirement.

Testing with the new required loads must not result in a ''hazardous condition,'' as defined in the general requirements, or result in a structural failure, such as fasteners breaking or disengaging, or seams separating when tested in accordance with the dynamic and static load testing methods. Additionally, dynamic and static load testing must not result in adjustable sections of support/shoulder straps slipping more than 1 inch per strap from their original adjusted position after testing.

Fastener Strength and Strap Retention—ASTM F2236–13 added a new component-level performance requirement to evaluate the strength of fasteners and strap retention to help prevent falls. Products recalled due to an occupant fall hazard were caused by broken fasteners that passed the static and dynamic performance requirements in ASTM F2236–10. Accordingly, the new performance requirement, section 6.4 of ASTM F2236–13, states that load-bearing fasteners at the shoulder and waist of soft infant and toddler carriers, such as buckles, loops, and snaps, may not break or disengage, nor may their straps slip more than 1 inch when subjected to an 80-pound pull force. Adjustable leg opening fasteners must also be tested, but are subjected to lower loads, a 45-pound pull force, because these fasteners do not carry the same load as fasteners at the shoulders and waist. When tested, fasteners must not break or disengage, and adjustable elements must not slip more than 1 inch.

Unbounded Leg Opening—ASTM F2236–13 clarifies the unbounded leg opening test procedure to improve test repeatability. An unbounded leg opening must not allow complete passage of a truncated test cone that is 4.7 inches long, with a major diameter of 4.7 inches and a minor diameter of 3 inches. The test cone is pulled through the leg opening with a 5-pound force for 1 minute.

Marking, Labeling, and Instructional Literature. ASTM F2236–13 requires that each product and its retail package be marked or labeled with certain information and warnings. The warning label requirement was updated to address fall and suffocation hazards. The warning label must provide a fall hazard statement addressing that infants can fall through wide leg openings or out of the carrier. The following fall-related warnings must be addressed on the warning label: adjust leg openings to fit baby's legs snugly; before each use, make sure all [fasteners/knots] are secure; take special care when leaning or walking; never bend at waist, bend at knees; only use this carrier for children between __ lbs. and __ lbs. Additionally, a suffocation hazard statement must

address that infants under 4 months old can suffocate in the carrier if the child's face is pressed tightly against the caregiver's body. The warning label must also address the following suffocation-related warnings: do not strap infant too tightly against your body; allow room for head movement; keep infant's face free from obstructions at all times. Products must also contain an informational statement that a child must face toward the caregiver until he or she can hold his or her head upright. Instructional literature must be provided with all products that includes: assembly, use, maintenance and cleaning, and required warnings.

Additionally, ASTM F2236–13 now includes an example warning label that identifies more clearly the hazards, the consequences of ignoring the warning, and what to do to avoid the hazards. The format of the label was designed to convey more effectively these warnings to the caregiver (Fig. 1). The rectangular shape of this label may be altered to fit on shoulder straps, if the manufacturer chooses not to place label in the occupant space; however, the label must be placed in a prominent and conspicuous location where the caregiver will see it when placing the soft infant and toddler carrier on their body.

⚠ WARNING

FALL AND SUFFOCATION HAZARD

FALL HAZARD - Infants can fall through a wide leg opening or out of carrier.

- Adjust leg openings to fit baby's legs snugly.
- Before each use, make sure all ____ are secure.
- Take special care when leaning or walking.
- Never bend at waist; bend at knees.
- Only use this carrier for children between ___ lb. and ___ lb.

SUFFOCATION HAZARD – Infants under 4 months can suffocate in this product if face is pressed tight against your body.

- Do not strap infant too tight against your body.
- Allow room for head movement.
- Keep infant's face free from obstructions at all times.

Figure 1. ASTM F2236-13 Example Warning label.

V. Assessment of Voluntary Standard ASTM F2236–13

In this section of the preamble, we evaluate ASTM F2236–13 to determine whether adopting this voluntary standard as a mandatory standard will address the incidents described in section III of this preamble, or whether more stringent standards are required to reduce further the risk of injury associated with soft infant and toddler carriers.

A. Large Leg Openings

Twenty-three percent of the injuries (7 of 30), including three hospitalizations, were caused when a child fell out of a large leg opening. The last incident occurred in 2005, involving a product purchased initially in 2000. The prevalence of this hazard led to product recalls in 1999 (see section III.E above) and led to the creation of ASTM F2236, whose first performance requirement (6.1 and corresponding test 7.1) was developed to limit the size of a soft infant and toddler carrier leg opening. New reports involving the large leg opening hazard ceased within 2 years of the first version of ASTM F2236's publication in 2003. This, combined with CPSC detailed incident reviews, lead us to conclude that the current ASTM standard adequately addresses the large leg opening hazard scenario.

B. Structure, Fit, and Position

Thirty-three percent of injuries reported to the CPSC (10 of 30) were related to the structure of the occupant seat area; fit of the occupant in the carrier; and the position of the soft infant and toddler carrier or the position of the wearer, or the position of the child in the seat area. These incidents occurred, for example, when an infant tucked down into the carrier and the caregiver bent at the waist breaking the child's leg; an infant fell out of the top of the carrier when the caregiver bent forward abrasions and/or blisters on infants from prolonged rubbing against the carrier while in use; and when infants suffered leg circulation-related injuries. New language in ASTM F2236–13 requires that warning labels address ensuring that fasteners and knots are secure before each use, taking special care when leaning or walking, and bending at the knees, not at the waist, while wearing the carrier. The standard also includes requirements on the format of the label to enhance the label's effectiveness (Fig. 1).

Updated warning language on the product and in the instructional literature may address hazards arising from structure, fit, and position problems if consumers read, understand, and comply with the warnings. The diverse size of potential occupants, the broadrange of caregiver sizes and shapes, and numerous possible motions and activities that could lead to injury cannot be reliably replicated in a laboratory setting, making development of a repeatable test for structure, fit, and position types of injuries prohibitively difficult. A warning label would likely not address the hazard with circulation-related injuries because that hazard may be due to a design issue. The Commission will

continue to study incoming reports of leg circulation-related injuries and determine whether any additional action is necessary.

C. Fasteners

Twenty percent of the injuries (6 of 30) were caused by fastener failures when a fastener suddenly broke or separated and the child fell to the ground. Although no hospitalizations resulted from breaking fasteners, three children suffered fractured collarbones, along with contusions and abrasions to heads and faces. The caregiver in a majority of the incidents was able to catch the child and prevent a fall. Fastener failures led to four of the five voluntary product recalls conducted since 2005.

ASTM F2236–13 addresses the hazards posed by fastener failures with a new performance requirement for fastener strength and strap retention, published in section 6.4 and a new test in section 7.7. New requirements state that all load-bearing fasteners, such as buckles, loops, and snaps may not break or disengage, nor may their straps slip more than 1 inch, when an 80-pound pull force is applied across the fasteners. An exception is made for adjustable leg opening fasteners, which must be subjected to a 45-pound pull force. Adjustable leg opening fasteners see substantially less load than other load-bearing fasteners during foreseeable use and abuse, such as fasteners securing shoulder and waist straps. The fastener strength and strap retention requirements do not apply to non-load-bearing fasteners that attach accessories, such as bibs, rain hoods, and toys to the soft infant and toddler carrier. The Commission believes that the inclusion of this new requirement in ASTM F2236–13 will adequately address the fall hazard related to fastener failures.

D. Design and Finish

Seven percent of the soft infant and toddler injuries (2 of 30) are attributable to design and finish issues. Complaints include inadequate back support, rough fabric, poor air flow in the carrier insert, and one report of high lead levels in a zipper pull. The injuries consist of a pinched finger and a cut on the nose. ASTM F2236–13 includes language prohibiting sharp points and edges, but the standard does not specifically mention pinching. A pinching-shearing-scissoring hazard exists typically in products with rigid parts that move past one another; such a hazard does not generally exist with soft products. No changes to the voluntary standard for design and finish issues are recommended at this time. Section 101 of the CPSIA requires that children's products, such as soft infant and toddler carriers, not contain lead content in excess of 100 parts per million. Accordingly, such requirement does not need to be repeated in ASTM F2236–13.

E. Stitching/Seams

Although only three percent of the injuries (1 of 30) involve stitching and seams, 11 percent of the total soft infant carrier reports (10 of 93) describe incidents in which stitching became undone or seams ripped, resulting in other components, like straps, becoming detached. One injury was reported when a seam failed, causing a 4-month-old child to fall and receive minor contusions. The new fastener strength test, and the more stringent dynamic and static load tests in sections 7.7 and 7.2 of ASTM F2236–13, respectively, all apply loads to soft infant and toddler carrier seams and sewn attachment points. The Commission believes that incidents related to ripping seams are adequately addressed by these new requirements in the voluntary standard, and therefore, we are not proposing any additional changes at this time.

F. Straps

Although there were no injuries related to soft infant carrier straps, nine percent of the reported incidents (8 of 93) involve issues with straps. The problems reported include broken strap length adjustment mechanisms and straps that permit unexpected slippage. The new fastener strength and strap retention requirements, and the more stringent dynamic and static load tests in sections 7.7 and 7.2 of ASTM F2236–13, respectively, all apply loads to soft infant and toddler carrier straps, and require that they not break or allow more than 1 inch of slippage. Accordingly, the Commission believes that incidents related to breaking and slipping straps are adequately addressed by these new requirements in the voluntary standard and is not proposing any additional changes at this time.

G. Other

Thirteen percent of the injury reports (4 of 30), including two deaths, contain insufficient information for the CPSC to determine the exact nature of the product's contribution to the incident. This category includes two fatalities and four injuries, including two hospitalizations. The two fatalities discussed above in section III.A, both involving suffocation, are included in this category. In each case, CPSC staff concluded that there were too many confounding factors reported to determine that a specific factor contributed predominantly to the deaths. ASTM F2236–13 does, however, address in the warning label requirements a suffocation hazard arising from use of soft infant and toddler carriers. The new warning label requirements state that products must address the fact that infants under 4 months old can suffocate if their face is too tight against a caregiver's body, and the label also advises caregivers not to strap the infant too tightly against the body to allow room for head movement and to keep an infant's face free from obstruction at all times.

VI. Effective Date

The Administrative Procedure Act (APA) generally requires that the effective date of the rule be at least 30 days after publication of the final rule. 5 U.S.C. 553(d). To allow time for manufacturers of soft infant and toddler products to come into compliance, the Commission proposes that the standard become effective 6 months after publication of a final rule in the **Federal Register**. The Commission invites comment on whether 6 months will be sufficient time for soft infant and toddler carrier manufacturers to come into compliance with the rule.

VII. Regulatory Flexibility Act

A. Introduction

The Regulatory Flexibility Act (RFA) requires that proposed rules be reviewed for their potential economic impact on small entities, including small businesses. Section 603 of the RFA generally requires that CPSC staff prepare an initial regulatory flexibility analysis and make it available to the public for comment when the general notice of proposed rulemaking is published. The initial regulatory flexibility analysis must describe the impact of the proposed rule on small entities and identify any alternatives that may reduce the impact. Specifically, the initial regulatory flexibility analysis must contain:

- A description of, and where feasible, an estimate of the number of small entities to which the proposed rule will apply;
- a description of the reasons why action by the agency is being considered;
- a succinct statement of the objectives of, and legal basis for, the proposed rule;
- a description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities subject to

the requirements and the types of professional skills necessary for the preparation of reports or records; and

• identification, to the extent possible, of all relevant federal rules which may duplicate, overlap, or conflict with the proposed rule.

B. Market for Soft Infant and Toddler Carriers

Soft infant and toddler carriers are generally produced and/or marketed by juvenile product manufacturers and distributors. Several of these firms focus exclusively on soft infant and toddler carriers, as well as substitute products, such as slings. CPSC staff believes that there are at least 39 suppliers to the U.S. market. Thirty-one domestic firms supply soft infant and toddler carriers to the U.S. market: 15 are domestic manufacturers; eight are domestic importers; and the supply sources of eight domestic firms are unknown. Five foreign firms supply soft infant and toddler carriers to the U.S. market: three are foreign manufacturers; one is a foreign importer; and one firm has an unknown supply source. Insufficient information is available to categorize the remaining three firms.[2]

According to a 2005 survey conducted by the American Baby Group (*2006 Baby Products Tracking Study*), 51 percent of new mothers own soft infant and toddler carriers.[3] Approximately 30 percent of soft infant and toddler carriers were handed down or purchased secondhand.[4] Thus, about 70 percent of soft infant and toddler carriers were acquired new. This suggests that approximately 1.5 million soft infant and toddler carriers are sold to households annually ($.51 \times .70 \times 4.1$ million births per year).[5]

Many soft infant and toddler carriers have expanded their maximum weight limits in recent years to accommodate older children. Staff believes, however, that most adult users would not be comfortable carrying older, heavier children in soft infant and toddler carriers. This belief is supported by a lack of incident data for children over 2 years old. It appears that soft infant and toddler carriers are used during a child's first year, with some caregivers continuing to use these products into the second year. We do not know the proportion who continues to use these products into the second year; accordingly, we estimate risk under the assumption that approximately 25–50 percent will do so. Based on data from the *2006 Baby Products Tracking Study,* approximately 2.1 million soft infant and toddler carriers are owned by new mothers. Therefore, approximately 2.6–3.2 million households have soft infant and toddler carriers available for use annually. Based on Epidemiology staff's estimate of 1,400 injuries treated nationally in emergency departments from 1999 to 2011, it is estimated that an average of 108 emergency department-treated injuries involving children under age 2 related to soft infant and toddler carriers are treated annually. Therefore, about 0.34–0.40 emergency department-treated injuries may occur annually for every 10,000 soft infant and toddler carriers available for use in the households of new (and second year) mothers.

C. Reason for Agency Action and Legal Basis for the Draft Proposed Rule

The Danny Keysar Child Product Safety Notification Act, section 104 of the CPSIA, requires the CPSC to promulgate mandatory standards that are substantially the same as, or more stringent than, the voluntary standard for a durable infant or toddler product. CPSC staff worked closely with ASTM to develop the new requirements and test procedures that have been incorporated into ASTM F2236–13, which forms the basis of the proposed rule.

D. Requirements of the Proposed Rule

The requirements of the proposed rule are set forth above in section IV.B.2 of this preamble, which describes ASTM F2236–13.

E. Other Federal Rules

Section 14(a)(2) of the CPSA requires every manufacturer and private labeler of a children's product that is subject to a children's product safety rule to certify, based on third party testing conducted by a CPSC-accepted laboratory, that the product complies with all applicable children's product safety rules. Section 14(i)(2) of the CPSA requires the Commission to establish protocols and standards, by rule, for among other things, ensuring that a children's product is tested periodically and where there has been a material change in the product, and for safeguarding against the exercise of undue influence on a conformity assessment body by a manufacturer or private labeler. A final rule implementing sections 14(a)(2) and 14(i)(2) of CPSA, *Testing and Labeling Pertaining to Product Certification,* 16 CFR part 1107, became effective on February 13, 2013 (the 1107 rule).

Soft infant and toddler carriers will be subject to a mandatory children's product safety rule, so they will also be subject to the third party testing requirements of section 14 of the CPSA and the 1107 rule when the final rule and the notice of requirements become effective.

F. Impact on Small Businesses

Under U.S. Small Business Administration (SBA) guidelines, a manufacturer of soft infant and toddler carriers is small if it has 500 or fewer employees; and importers and wholesalers are considered small if they have 100 or fewer employees. Based on these guidelines, 26 of the 31 domestic firms supplying soft infant and toddler carriers to the U.S. market are small firms—12 manufacturers, six importers, and eight firms whose supply source is unknown. Additional unknown small soft infant and toddler carrier suppliers may operate in the U.S. market as well.

Small Manufacturers. The expected impact of the proposed rule on small manufacturers will differ, based on whether their soft infant and toddler carriers are already compliant with ASTM F2236–10. Although ASTM F2236–12 was published in December 2012, and ASTM F2236–13 was published in March 2013, new standards are not in effect until 6 months after publication. Accordingly, firms are likely to be still testing to ASTM F2236–10. In general, firms whose soft infant and toddler carriers meet the requirements of ASTM F2236–10 are likely to continue to comply with the voluntary standard as new versions are published. In addition, they are likely to meet any new standard within 6 months because this is the amount of time JPMA allows for products in its certification program to shift to a new standard. Many of these firms are active in the ASTM standard development process, and compliance with the voluntary standard is part of an established business practice.

[2] Staff made these determinations using information from Dun & Bradstreet and Reference USAGov, as well as firm Web sites.

[3] The data collected for the *Baby Products Tracking Study* does not represent an unbiased statistical sample. The sample of 3,600 new and expectant mothers is drawn from American Baby magazine's mailing lists. Also, because the most recent survey information is from 2005, it may not reflect the current market.

[4] The data on secondhand products for new mothers was not available. Instead, data for new mothers and experienced mothers were combined and broken down into first-time mothers and experienced mothers. Data for first-time mothers and experienced mothers have been averaged to calculate the approximate percentage of soft infant and toddler carriers that were handed down or purchased secondhand.

[5] U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), National Center for Health Statistics, National Vital Statistics System, ''Births: Final Data for 2009,'' *National Vital Statistics Reports* Volume 60, Number 1 (November 2011): Table I. Number of live births in 2009 is rounded from 4,130,665.

The impact on seven of 12 domestic manufacturers who comply with ASTM F2236–10 is expected to be small. Firms already in compliance with ASTM F2236–10 may require slight, if any, modifications, in order to bring their product(s) into compliance with the current voluntary standard. Any strap/fastener modifications are expected to incur minimal costs, as are changes to the warning label.

Meeting ASTM F2236–13's requirements could necessitate some product redesign for five of the 12 domestic manufacturers who are not believed to be compliant with ASTM F2236–10. These redesigns would likely involve adding or changing straps, fasteners, or fabrics; and partial redesigns are generally less expensive than complete redesigns, based on past discussions with manufacturers. For the types of changes that might be required to be made to these products, staff does not believe that complete redesigns (*e.g.,* engineering time, prototype development, and tooling) would be required for any known products. Therefore, in most cases, the impact of the proposed rule is not expected to have a significant effect on products that are not believed to be compliant with ASTM F2236–10.

It is possible that some firms whose soft infant and toddler carriers are neither certified as compliant, nor claim compliance with ASTM F2236–10 (or a similar standard), in fact, are compliant with the standard. CPSC staff has identified many such cases with other infant and toddler products. To the extent that some of these firms may supply compliant soft infant and toddler carriers and have developed a pattern of compliance with the voluntary standard, the direct impact of the proposed rule will be less significant than described above.

Eight small firms have unknown supply sources, three of which appear to be compliant with ASTM F2236–10. If these firms are manufacturers, they will be affected as described above. If these firms are distributers or wholesalers, the impact will be similar to the impact on importers, as discussed below.

In addition to the direct impact of the proposed rule, indirect impacts exist. These impacts are considered indirect because they do not arise directly as a consequence of the proposed rule's requirements. Once the rule becomes final and the notice of requirements is in effect, all manufacturers will be subject to the additional costs associated with the third party testing and certification requirements. This will include any physical and mechanical test requirements specified in the final rule. Because lead and phthalates testing are already required for soft infant and toddler products, they are not included in this discussion.

Staff estimates that testing to the ASTM voluntary standard could cost about $500–$600 per model sample. On average, each small domestic manufacturer supplies two different models of soft infant and toddler carriers to the U.S. market annually. Therefore, if third party testing is conducted every year on a single sample for each model, third party testing costs for each manufacturer would be about $1,000–$1,200 annually. Based on a review of firms' revenues, the impact of third party testing to ASTM F2236–13—if only one soft carrier sample per model is required—is unlikely to be significant. However, these costs could be more significant if multiple models are needed for testing.

Small Importers. Most importers would not experience significant impacts as a result of the proposed rule. Five of the six small importers are believed to be compliant with the voluntary standard. In the absence of regulation, these firms would likely continue to comply with the voluntary standard as it evolves and would likely comply with the final mandatory standard as well. The remaining importer might need to find an alternate source of soft infant and toddler carriers if its existing supplier does not come into compliance with the requirements of the proposed rule. Alternatively, the firm may discontinue importing soft infant and toddler carriers altogether and perhaps substitute another product.

As is the case with manufacturers, all importers will be subject to third party testing and certification requirements, and consequently, they will experience the associated costs if their supplying foreign firm(s) does not perform third party testing. The resulting costs could have a significant impact on a few small importers who must perform the testing themselves if more than one sample per model is required. In addition, the impacts could be higher than those incurred by domestic manufacturers if importers have to test each batch imported in the case where the foreign manufacturer does not conduct testing.

G. Alternatives

Under the Danny Keysar Child Product Safety Notification Act, section 104 of the CPSIA, one alternative would be to set an effective date later than the proposed 6 months, which is generally considered sufficient time for suppliers to come into compliance with a proposed durable infant and toddler product rule. Setting a later effective date would allow suppliers additional time to modify and/or develop compliant soft infant and toddler carriers and spread the associated costs over a longer period of time.

VIII. Environmental Considerations

The Commission's regulations address whether we are required to prepare an environmental assessment or an environmental impact statement. If our rule has ''little or no potential for affecting the human environment,'' it will be categorically exempted from this requirement. 16 CFR 1021.5(c)(1). The proposed rule falls within the categorical exemption.

IX. Paperwork Reduction Act

The proposed rule contains information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). In this document, pursuant to 44 U.S.C. 3507(a)(1)(D), we set forth:

- A title for the collection of information;
- A summary of the collection of information;
- A brief description of the need for the information and the proposed use of the information;
- A description of the likely respondents and proposed frequency of response to the collection of information;
- An estimate of the burden that shall result from the collection of information; and
- Notice that comments may be submitted to the OMB.

Title: Safety Standard for Soft Infant and Toddler Carriers

Description: The proposed rule would require each soft infant and toddler carrier to comply with ASTM F2236–13, *Standard Consumer Safety Specification for Soft Infant and Toddler Carriers.* Sections 8.1 and 9.1 of ASTM F2236–13 contain requirements for marking, labeling, and instructional literature that are disclosure requirements, thus falling within the definition of ''collections of information'' at 5 C.F.R. 1320.3(c).

Description of Respondents: Persons who manufacture or import soft infant and toddler carriers.

Estimated Burden: We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

16 CFR Section	Number of respondents	Frequency of responses	Total annual responses	Hours per response	Total burden hours
1226	39	2	78	1	78

Our estimate is based on the following:

Section 8.1 of ASTM F2236–13 requires that all soft infant and toddler carrier products and their retail packaging be marked or labeled as follows: the manufacturer, distributor, or seller name, and either the place of business (city, state, mailing address including zip code), or telephone number, or both; and a code mark or other means that identifies the date (month and year as a minimum) of manufacture.

CPSC is aware of 39 firms that supply soft infant and toddler carriers in the U.S. market. All 39 firms are assumed to use labels on their products and on their packaging already, but they might need to make some modifications to their existing labels. The estimated time required to make these modifications is about 1 hour per model. Each of these firms supplies an average of two different models of soft infant and toddler carrier; therefore, the estimated burden hours associated with labels is 1 hour × 39 firms × 2 models per firm = 78 hours annually.

We estimate the hourly compensation for the time required to create and update labels is $27.92 (U.S. Bureau of Labor Statistics, ''Employer Costs for Employee Compensation,'' September 2012, Table 9, total compensation for all sales and office workers in goods-producing private industries: *http://www.bls.gov/ncs/*). Therefore, the estimated annual cost to industry associated with the labeling requirements is $2,177.76 ($27.92 per hour × 78 hours = $2,177.76). No operating, maintenance, or capital costs are associated with the collection.

Section 9.1 of ASTM F2236–13 requires that all soft infant and carrier products provide instructions that are easy to read and understand. Where applicable, instructions for assembly, use, maintenance and cleaning of the product, and warnings, must also be included. Soft infant and toddler carriers are products that do not generally require installation but require instruction for proper use, fit, and adjustment on a caregiver's body. Under the OMB's regulations (5 CFR 1320.3(b)(2)), the time, effort, and financial resources necessary to comply with a collection of information that would be incurred by persons in the ''normal course of their activities'' are excluded from a burden estimate, where an agency demonstrates that the disclosure activities required to comply are ''usual and customary.'' Therefore, because we are unaware of soft infant and toddler carriers that lack any instructions to the user about proper use, fit, and assembly, we estimate tentatively that there are no burden hours associated with section 9.1 of ASTM F 2236–13 because any burden associated with supplying instructions with soft infant and toddler carriers would be ''usual and customary'' and would not fit within the definition of ''burden'' under the OMB's regulations.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), we have submitted the information collection requirements of this rule to OMB for review. Interested persons are requested to submit comments regarding information collection by May 6, 2013, to the Office of Information and Regulatory Affairs, OMB (see the **ADDRESSES** section at the beginning of this notice).

Pursuant to 44 U.S.C. 3506(c)(2)(A), we invite comments on:

- Whether the collection of information is necessary for the proper performance of the CPSC's functions, including whether the information will have practical utility;
- the accuracy of the CPSC's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- ways to enhance the quality, utility, and clarity of the information to be collected;
- ways to reduce the burden of the collection of information on respondents, including the use of automated collection techniques, when appropriate, and other forms of information technology; and
- the estimated burden hours associated with label modification, including any alternative estimates.

X. Preemption

Section 26(a) of the CPSA, 15 U.S.C. 2075(a), provides that where a consumer product safety standard is in effect and applies to a product, no state or political subdivision of a state may either establish or continue in effect a requirement dealing with the same risk of injury unless the state requirement is identical to the federal standard. Section 26(c) of the CPSA also provides that states or political subdivisions of states may apply to the Commission for an exemption from this preemption under certain circumstances. Section 104(b) of the CPSIA refers to the rules to be issued under that section as ''consumer product safety rules,'' thus implying that the preemptive effect of section 26(a) of the CPSA would apply. Therefore, a rule issued under section 104 of the CPSIA will invoke the preemptive effect of section 26(a) of the CPSA when it becomes effective.

XI. Certification and Notice of Requirements (NOR)

Section 14(a) of the CPSA imposes the requirement that products subject to a consumer product safety rule under the CPSA, or to a similar rule, ban, standard or regulation under any other act enforced by the Commission, must be certified as complying with all applicable CPSC-enforced requirements. 15 U.S.C. 2063(a). Section 14(a)(2) of the CPSA requires that certification of children's products subject to a children's product safety rule be based on testing conducted by a CPSC-accepted third party conformity assessment body. Section 14(a)(3) of the CPSA requires the Commission to publish a notice of requirements (NOR) for the accreditation of third party conformity assessment bodies (or laboratories) to assess conformity with a children's product safety rule to which a children's product is subject. The proposed rule for 16 CFR part 1226, ''Safety Standard for Soft Infant and Toddler Carriers,'' when issued as a final rule, will be a children's product safety rule that requires the issuance of an NOR.

Effective June 10, 2013, the Commission published a final rule, *Requirements Pertaining to Third Party Conformity Assessment Bodies,* 78 FR 15836 (March 12, 2013), which codifies 16 CFR part 1112. Part 1112 establishes requirements for accreditation of third party conformity assessment bodies (or laboratories) to test for conformance with a children's product safety rule in accordance with Section 14(a)(2) of the CPSA. The final rule also codifies all of the NORs that the CPSC has published to date. All new NORs, such as the soft infant and toddler carrier standard,

require an amendment to part 1112. Accordingly, the proposed rule would amend part 1112 to include the soft infant and toddler standard along with the other children's product safety rules for which the CPSC has issued NORs.

Laboratories applying for acceptance as a CPSC-accepted third party conformity assessment body to test to the new standard for soft infant and toddler carriers would be required to meet the third party conformity assessment body accreditation requirements in part 1112. When a laboratory meets the requirements as a CPSC-accepted third party conformity assessment body, it can apply to the CPSC to have 16 CFR part 1226, *Safety Standard for Soft Infant and Toddler Carriers*, included in its scope of accreditation of CPSC safety rules listed for the laboratory on the CPSC Web site at: *www.cpsc.gov/labsearch*.

CPSC staff previously conducted an analysis of the potential impacts on small entities of the proposed rule for part 1112, and published an Initial Regulatory Flexibility Analysis (IRFA) in 77 FR 31086, 31123–26 (May 24, 2012). The IRFA concluded that the requirements in part 1112 would not have a significant adverse impact on a substantial number of small laboratories because no requirements are imposed on laboratories that do not intend to provide third party testing services under Section 14(a)(2) of the CPSA. The only laboratories that are expected to provide such services are those that anticipate receiving sufficient revenue from providing the mandated testing to justify accepting the requirements as a business decision. Laboratories that do not expect to receive sufficient revenue from these services to justify accepting these requirements would likely not pursue accreditation for this purpose.

Amending part 1112 to include the NOR for the soft infant and toddler standard would also not have a significant adverse impact on small laboratories. Based upon the number of laboratories in the United States that have applied for CPSC acceptance of the accreditation to test for conformance to other juvenile product standards, we expect that only a few laboratories will seek CPSC acceptance of their accreditation to test for conformance with the soft infant and toddler standard. Most of these laboratories already will have been accredited to test for conformance to other juvenile product standards, and the only cost to them would be the cost of adding the soft infant and toddler standard to their scope of accreditation. As a consequence, the Commission could certify that the proposed NOR for the soft infant and toddler standard will not have a significant impact on a substantial number of small entities.

The final NOR will base the CPSC laboratory accreditation requirements on the performance standard set forth in the final rule for the safety standard for soft infant and toddler carriers and the test methods incorporated within that standard. The Commission may recognize limited circumstances in which it will accept certification based on product testing conducted before the Commission's acceptance of accreditation of laboratories for testing soft infant and toddler carriers (also known as retrospective testing) in the final NOR. The Commission seeks comments on any issues regarding the testing requirements of the proposed rule for soft infant and toddler carriers and the accompanying proposed NOR.

XII. Request for Comments

This proposed rule begins a rulemaking proceeding under section 104(b) of the CPSIA to issue a consumer product safety standard for soft infant and toddler carriers. We invite all interested persons to submit comments on any aspect of the proposed rule. Comments should be submitted in accordance with the instructions in the **ADDRESSES** section at the beginning of this notice.

List of Subjects

16 CFR Part 1112

Administrative practice and procedure, Audit, Consumer protection, Reporting and recordkeeping requirements, Third party conformity assessment body.

16 CFR Part 1226

Consumer protection, Imports, Incorporation by reference, Infants and Children, Labeling, Law Enforcement, and Toys.

For the reasons discussed in the preamble, the Commission proposes to amend Title 16 of the Code of Federal Regulations by amending part 1112 and adding a new part 1226, as follows:

PART 1112—REQUIREMENTS PERTAINING TO THIRD PARTY CONFORMITY ASSESSMENT BODIES

■ 1. The authority citation for part 1112 continues to read as follows:

Authority: 15 U.S.C. 2063.; Pub. L. 110–314, section 3, 122 Stat. 3016, 3017 (2008)

■ 2. In § 1112.15 add paragraph (b)(36) to read as follows:

§ 1112.15 When can a third party conformity assessment body apply for CPSC acceptance for a particular CPSC rule and/or test method?

* * * * *

(b) * * *

* * * * *

(36) 16 CFR part 1226, Safety Standard for Soft Infant and Toddler Carriers.

■ 3. Add Part 1226 to read as follows:

PART 1226—SAFETY STANDARD FOR SOFT INFANT AND TODDLER CARRIERS

Sec.
1226.1 Scope.
1226.2 Requirements for Soft Infant and Toddler Carriers.

Authority: The Consumer Product Safety Improvement Act of 2008, Pub. L. 110–314, § 104, 122 Stat. 3016 (August 14, 2008); Pub. L. 112–28, 125 Stat. 273 (August 12, 2011).

§ 1226.1 Scope.

This part establishes a consumer product safety standard for soft infant and toddler carriers.

§ 1226.2 Requirements for Soft Infant and Toddler Carriers.

(a) Each soft infant and toddler carrier must comply with all applicable provisions of ASTM F2236–13, Standard Consumer Safety Specification for Soft Infant and Toddler Carriers, approved on March 1, 2013. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from ASTM International, 100 Bar Harbor Drive, P.O. Box 0700, West Conshohocken, PA 19428; *http://www.astm.org/cpsc.htm*. You may inspect a copy at the Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone 301–504–7923, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal regulations/ibr_locations.html*.

(b) Reserved

Dated: March 29, 2013.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2013–07687 Filed 4–4–13; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 53

[REG–106499–12]

RIN 1545–BL30

Community Health Needs Assessments for Charitable Hospitals

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations that provide guidance to charitable hospital organizations on the community health needs assessment (CHNA) requirements, and related excise tax and reporting obligations, enacted as part of the Patient Protection and Affordable Care Act of 2010. These proposed regulations also clarify the consequences for failing to meet these and other requirements for charitable hospital organizations. These regulations will affect charitable hospital organizations.

DATES: Comments and requests for a public hearing must be received by July 5, 2013.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–106499–12), room 5203, Internal Revenue Service, PO Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG–106499–12), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC, or sent electronically via the Federal eRulemaking Portal at *http://www.regulations.gov* (IRS REG–106499–12).

FOR FURTHER INFORMATION CONTACT: Concerning these proposed regulations, Amy F. Giuliano or Preston J. Quesenberry at (202) 622–6070; concerning submissions of comments and requests for a public hearing, Oluwafunmilayo Taylor at (202) 622–7180 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in this notice of proposed rulemaking has been submitted to the Office of Management and Budget for review and approval under OMB control number 1545–0047, in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)). Comments on the collection of information should be sent to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, SE:W:CAR:MP:T:T:SP, Washington, DC 20224. Comments on the collection of information should be received by June 4, 2013. Comments are specifically requested concerning:

Whether the proposed collection of information is necessary for the proper performance of the functions of the Internal Revenue Service, including whether the information will have practical utility;

The accuracy of the estimated burden associated with the proposed collection of information;

How the quality, utility, and clarity of the information to be collected may be enhanced;

How the burden of complying with the proposed collection of information may be minimized, including through forms of information technology; and

Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

The collection of information in these proposed regulations is in § 1.501(r)-3 and § 1.6033–2(a)(2)(ii)(*l*). The collection of information flows from sections 501(r)(3) and 6033(b)(15) of the Internal Revenue Code (Code), which require a hospital organization to conduct a CHNA and adopt an implementation strategy to meet the community health needs identified through the CHNA at least once every three years, report on its annual information return how it is meeting the needs identified through the CHNA, and attach to its annual information return a copy of its audited financial statements. The expected recordkeepers are hospital organizations described in sections 501(c)(3) and 501(r)(2).

The following estimates are based on information that is available to the IRS and averaged over a three-year time period, to reflect the fact that the information collection generally will be spread over the statutory three-year cycle during which a hospital organization is required to conduct a CHNA and adopt an implementation strategy. A particular hospital organization may require more or less time, depending on the circumstances.

Estimated number of recordkeepers: 3,377.

Estimated average annual burden hours per recordkeeper: 80 hours.

Estimated total annual recordkeeping burden: 270,160 hours.

The burden for the collection of information contained in the proposed amendments to § 1.6033–2 will be reflected in the burden on Form 990, ''Return of Organization Exempt from Tax,'' after it is revised to require the additional information in the regulation.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by the Office of Management and Budget.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and return information are confidential, as required by section 6103.

Background

The Patient Protection and Affordable Care Act, Public Law 111–148 (124 Stat. 119 (2010)) (the ''Affordable Care Act''), enacted section 501(r) of the Code, which imposes additional requirements on charitable hospital organizations. Section 501(r)(1) states that a hospital organization described in section 501(r)(2) will not be treated as a tax-exempt organization described in section 501(c)(3) unless the organization meets the requirements of section 501(r)(3) through 501(r)(6). The Affordable Care Act did not otherwise affect the substantive standards for tax exemption that charitable hospital organizations are required to meet under section 501(c)(3).

Section 501(r)(2)(A) defines a hospital organization as: (i) An organization that operates a facility required by a state to be licensed, registered, or similarly recognized as a hospital; and (ii) any other organization that the Secretary determines has the provision of hospital care as its principal function or purpose constituting the basis for its exemption under section 501(c)(3).

Section 501(r)(2)(B)(i) requires a hospital organization that operates more than one hospital facility to meet the requirements of section 501(r) separately with respect to each hospital facility. Section 501(r)(2)(B)(ii) provides that a hospital organization will not be treated as described in section 501(c)(3) with respect to any hospital facility for which the requirements of section 501(r) are not separately met.

Section 501(r)(3) requires a hospital organization to conduct a CHNA at least once every three years and adopt an implementation strategy to meet the community health needs identified through the CHNA. The CHNA must take into account input from persons who represent the broad interests of the community served by the hospital

facility, including those with special knowledge of or expertise in public health. The CHNA must also be made widely available to the public.

Section 4959 imposes a $50,000 excise tax on a hospital organization that fails to meet the CHNA requirements for any taxable year. A hospital organization must report the amount of any excise tax imposed on it under section 4959 on its annual information return (that is, Form 990, ''Return of Organization Exempt From Income Tax,'' and related schedules) pursuant to section 6033(b)(10)(D).

Section 6033(b)(15)(A) requires a hospital organization to report on its Form 990 a description of how the organization is addressing the needs identified in each CHNA and a description of any needs that are not being addressed together with the reasons why the needs are not being addressed.

Section 6033(b)(15)(B) requires a hospital organization to file with its Form 990 a copy of its audited financial statements (or, in the case of an organization the financial statements of which are included in consolidated financial statements with other organizations, its consolidated financial statements).

Notice 2010–39

In May 2010, the Department of the Treasury (''Treasury Department'') and the IRS issued Notice 2010–39 (2010–24 IRB 756 (May 27, 2010)), which solicited comments regarding the application of the additional requirements imposed by section 501(r). The Treasury Department and the IRS received approximately 125 comments in response to Notice 2010–39 and considered the comments relating to the consequences for failing a section 501(r) requirement in drafting these proposed regulations. The principal comments considered are discussed in this preamble under Explanation of Provisions.

Notice 2011–52

In July 2011, the Treasury Department and the IRS issued Notice 2011–52 (2011–30 IRB 60 (July 8, 2011)), which addressed the CHNA requirements of section 501(r)(3). Notice 2011–52 described provisions related to the CHNA requirements that the Treasury Department and the IRS anticipated would be included in these proposed regulations and solicited comments from the public. Specifically, Notice 2011–52 described anticipated regulatory provisions regarding the documentation of a CHNA, how and when a CHNA is conducted, the community served by a hospital facility, persons representing the broad interests of the community, making a CHNA widely available to the public, the implementation strategy, excise taxes on failures to meet the CHNA requirements, reporting requirements related to CHNAs, and the effective dates of the CHNA provisions. The Treasury Department and the IRS received more than 80 comments in response to Notice 2011–52. The principal comments considered in drafting these proposed regulations on the CHNA requirements are discussed in this preamble under Explanation of Provisions.

Notice 2011–52 provided that hospital organizations could rely on the anticipated regulatory provisions described in the notice for any CHNA made widely available to the public, and any implementation strategy adopted, on or before the date that is six months after the date further guidance regarding the CHNA requirements is issued. Thus, hospital organizations may continue to rely on the interim guidance described in Notice 2011–52 for any CHNA made widely available to the public, and any implementation strategy adopted, on or before October 5, 2013.

Notice of Proposed Rulemaking on Section 501(r)(4) Through 501(r)(6)

On June 26, 2012, the Treasury Department and the IRS published a notice of proposed rulemaking in the **Federal Register** (REG–130266–11; 77 FR 38148) (''2012 proposed regulations'') that contains proposed regulations regarding the requirements of section 501(r)(4) (which requires hospitals to establish financial assistance and emergency medical care policies), section 501(r)(5) (which limits the amount hospitals can charge for certain care provided to individuals eligible for financial assistance), and section 501(r)(6) (which prohibits a hospital from engaging in extraordinary collection actions before making reasonable efforts to determine whether an individual is eligible for financial assistance).

The 2012 proposed regulations also provide guidance on the hospital organizations and facilities that must meet the section 501(r) requirements. In particular, the 2012 proposed regulations contain a definitions section that defines ''hospital organization,'' ''hospital facility,'' and other key terms used in the regulations. *See* § 1.501(r)–1 of the proposed regulations. In accordance with section 501(r)(2)(A)(i), the 2012 proposed regulations define ''hospital organization'' as an organization recognized (or seeking to be recognized) as described in section 501(c)(3) that operates one or more hospital facilities, including a hospital facility operated through a disregarded entity. Also in accordance with section 501(r)(2)(A)(i), the 2012 proposed regulations define ''hospital facility'' as a facility that is required by a state to be licensed, registered, or similarly recognized as a hospital. In addition, the 2012 proposed regulations note that references to a hospital facility taking certain actions are intended to include instances in which the hospital organization operating the hospital facility takes action through, or on behalf of, the hospital facility. These definitions and concepts generally apply for purposes of these proposed regulations on the CHNA requirements and the consequences for failing to meet the section 501(r) requirements, although these proposed regulations make minor amendments to the definitions of ''hospital facility'' and ''hospital organization'' contained in the 2012 proposed regulations, as discussed further in the ''Explanation of Provisions'' section of this preamble.

The comment period for the 2012 proposed regulations closed on September 24, 2012. The Treasury Department and the IRS have received more than 200 comments in response to the 2012 proposed regulations and are continuing to consider these comments as they work toward finalizing those proposed regulations. The Treasury Department and the IRS intend to finalize the 2012 proposed regulations in conjunction with the finalization of these proposed regulations.

Explanation of Provisions

These proposed regulations provide guidance on the CHNA requirements of section 501(r)(3), and on the related reporting obligations of section 6033. In addition, these proposed regulations provide guidance on the consequences described in sections 501(r)(1), 501(r)(2)(B), and 4959 for failing to satisfy any of the section 501(r) requirements, including the section 501(r)(4) through 501(r)(6) requirements addressed in the 2012 proposed regulations. These proposed regulations generally do not otherwise provide further guidance regarding the section 501(r)(4) through 501(r)(6) requirements. They do, however, make minor amendments to the definitions of ''hospital facility'' and ''hospital organization'' contained in the 2012 proposed regulations and also provide a new definition of ''operating'' a hospital facility that is applicable for purposes of all of the section 501(r) requirements.

In interpreting the CHNA requirements of section 501(r)(3), the Treasury Department and the IRS sought to preserve hospital facilities' flexibility to determine the best way to identify and meet the particular health needs of the specific communities they serve while requiring a transparent assessment process with ample opportunity for community input.

1. Hospital Facilities and Organizations

a. Hospital Organization for Purposes of Section 4959

Section 4959 imposes a $50,000 excise tax on ''a hospital organization to which section 501(r) applies'' that fails to meet the requirements of section 501(r)(3) for any taxable year. For purposes of section 501(r), the 2012 proposed regulations define the term ''hospital organization'' to mean an organization ''recognized (or seeking to be recognized) as described in section 501(c)(3)'' that operates one or more hospital facilities. These proposed regulations clarify that the section 4959 excise tax will apply to a hospital organization that fails to meet the section 501(r)(3) requirements during a taxable year in which its section 501(c)(3) status is revoked. These proposed regulations do not otherwise change the substance of the ''hospital organization'' definition contained in the 2012 proposed regulations.

b. Multiple Buildings Under a Single Hospital License

The definition of ''hospital facility'' in the 2012 proposed regulations provides that multiple buildings operated by a hospital organization under a single state license may be considered a single hospital facility. This special rule for multiple buildings was intended to allow flexibility but has the disadvantage of making it harder for the IRS and the public to understand and to evaluate the information reported on a hospital organization's Form 990, particularly if multiple buildings under a single state license are reported differently (as a single facility or as multiple facilities) from year to year. To increase the certainty and consistency in the designation of hospital facilities, these proposed regulations amend this definition to provide that multiple buildings operated by a hospital organization under a single state license ''are'' (rather than ''may be'') considered a single hospital facility. The Treasury Department and the IRS request comments regarding whether (and under what circumstances) a hospital organization should be able to treat multiple buildings under a single state license as separate hospital facilities for purposes of the CHNA and other section 501(r) requirements and, if so, how certainty and consistency in the designation of hospital facilities can be achieved.

c. Tribal Hospital Facilities

Several commenters recommended that these proposed regulations make clear that a hospital facility operated by an Indian tribe or tribal organization is not subject to the section 501(r) requirements, even if the hospital facility is part of an organization described in section 501(c)(3). These commenters stated that tribal hospital facilities are not typically ''required by a state to be licensed, registered, or similarly recognized as a hospital,'' as contemplated in section 501(r)(2)(A)(i). The Treasury Department and the IRS note that section 501(r)(2)(A)(i) refers only to a hospital facility licensed or registered by a state, not an Indian tribal government, and that section 7871 does not provide that an Indian tribal government is treated as a state for purposes of section 501(r). Accordingly, pending any future guidance regarding other categories of hospital organizations or facilities, a tribal facility that is not required by a state to be licensed, registered, or similarly recognized as a hospital is not a ''hospital facility'' for purposes of section 501(r), and a section 501(c)(3) organization will not be considered a ''hospital organization'' solely as a result of operating such a tribal facility.

d. Operating a Hospital Facility Through a Partnership

Notice 2011–52 stated the intention of the Treasury Department and the IRS to include within the definition of ''hospital organization'' any organization described in section 501(c)(3) that operates a hospital facility through a joint venture, limited liability company, or other entity treated as a partnership for federal tax purposes. Notice 2011–52 also requested comments regarding whether (and under what circumstances) an organization should not be considered to ''operate'' a hospital facility for purposes of section 501(r) as a result of its owning a small interest (other than a general partner or similar interest) in an entity treated as a partnership for federal tax purposes that operates the hospital facility.

In response to Notice 2011–52, a few commenters recommended that a hospital organization generally should not be considered to operate a hospital facility through a partnership when it holds a minority interest in that partnership. In defining ''minority interest,'' commenters suggested ownership thresholds ranging from less than 50 percent to less than 20 percent. Commenters stated that a hospital organization with such a minority interest in a hospital facility joint venture would not have the necessary control over the joint venture to ensure that the hospital facility in question complied with the requirements of section 501(r).

Another commenter recommended that section 501(r) should not apply to a hospital facility operated by a partnership if the partner described in section 501(c)(3) treats the income derived from that facility as unrelated business taxable income (UBTI) that is taxed under section 511. This commenter argued that the line on the applicability of section 501(r) should be drawn based on the taxability of the hospital facility's income rather than on the basis of a particular percentage of ownership.

Yet another commenter suggested that these proposed regulations should provide that an organization that owns a minority limited partnership interest in a partnership that operates a hospital facility should not be considered to ''operate'' that hospital facility for purposes of section 501(r) if the organization entered into the limited partnership agreement prior to the date section 501(r) was enacted (that is, March 23, 2010) and has a primary tax-exempt purpose other than the provision of community health care. As an example of such an organization, this commenter cited a university medical school that entered into a partnership agreement to operate a hospital facility that gives the university control over the joint venture sufficient to ensure the operation of the hospital facility furthers its exempt educational purpose, but insufficient to ensure the hospital facility is in compliance with section 501(r).

Rev. Rul. 2004–51 (2004–1 CB 974) provides that the activities of an entity that is treated as a partnership for federal tax purposes are treated as the activities of the tax-exempt partner for purposes of determining whether the tax-exempt partner is operated exclusively for exempt purposes and engages in an unrelated trade or business. *See also* Rev. Rul. 98–15 (1998–1 CB 718). Consequently, consistent with Notice 2011–52, these proposed regulations provide that, as a general rule, a hospital organization ''operates'' a hospital facility if it is a partner in a joint venture, limited liability company, or other entity treated as a partnership for federal income tax

purposes that operates the hospital facility.

However, in light of the comments received, these proposed regulations provide two exceptions to this general rule. First, as commenters observed, an organization without the control over the operation of a hospital facility sufficient to ensure that the hospital facility furthers an exempt purpose is unlikely to have the control sufficient to ensure compliance with section 501(r). As a general rule, if a tax-exempt partner does not have control sufficient to ensure that a trade or business activity regularly carried on by the partnership furthers (or is substantially related to) its exempt purposes, that activity will be considered an unrelated trade or business with respect to the tax-exempt partner. *See* Rev. Rul. 2004–51; Rev. Rul. 98–15. These proposed regulations provide that if a section 501(c)(3) partner of a partnership operating a hospital facility does not have control over the operation of the hospital facility sufficient to ensure that the operation of the hospital facility furthers an exempt purpose described in section 501(c)(3) and thus treats the operation of the hospital facility, including the facility's provision of medical care, as an unrelated trade or business, the hospital organization will not be considered to ''operate'' the hospital facility for purposes of section 501(r).

Second, as another commenter observed, some tax-exempt organizations may have entered into partnership arrangements prior to the enactment of section 501(r) that gave them control over a partnership sufficient to ensure that the partnership furthers charitable purposes other than the provision of community health care, but not sufficient to ensure compliance with section 501(r). In response to this comment, these proposed regulations provide a grandfather rule under which a hospital organization will not be considered to ''operate'' a hospital facility for purposes of section 501(r) if certain conditions are met. First, at all times since March 23, 2010, the hospital organization must have been organized and operated primarily for educational or scientific purposes and must not have engaged primarily in the operation of one or more hospital facilities. Second, pursuant to a partnership arrangement (including any side agreements) entered into before March 23, 2010, the hospital organization must not own more than 35 percent of the capital or profits interest in the partnership, not own a general partner or similar interest, and not have sufficient control over the operation of the hospital facility to ensure that the hospital facility complies with the requirements of section 501(r).

Finally, like both Notice 2011–52 and the 2012 proposed regulations, these proposed regulations make clear that a hospital organization operates a hospital facility if it operates a hospital facility through a wholly-owned entity that is disregarded as separate from the hospital organization for federal tax purposes.

e. Activities Unrelated to the Operation of a Hospital Facility

In response to Notice 2010–39, a few commenters asked whether the requirements of section 501(r) apply to those aspects of a hospital organization's operations that do not relate to the operation of a hospital facility. Section 501(r)(2)(B) provides that the requirements of section 501(r) apply separately with respect to each of the hospital facilities a hospital organization operates. Similarly, section 1.501(r)–2 of these proposed regulations (which describes consequences for failing to satisfy the requirements of section 501(r)) only applies to circumstances in which a hospital organization fails to meet one or more of the requirements of section 501(r) ''separately with respect to one or more hospital facilities'' it operates. Thus, the Treasury Department and the IRS intend that a hospital organization is not required to meet the requirements of section 501(r) with respect to any activities unrelated to the operation of a hospital facility. For example, if a hospital organization operates a facility that is not required to be licensed as a hospital by the state in which the facility is located, the hospital organization is not required to meet the requirements of section 501(r) with respect to that facility.

f. Authorized Body of a Hospital Organization or Facility

For purposes of determining whether a hospital organization has established a policy required under section 501(r)(4) for a hospital facility it operates, the 2012 proposed regulations would require an authorized body to adopt the policy for the hospital facility. The 2012 proposed regulations define the term ''authorized body'' to include: (1) The governing body (that is, the board of directors, board of trustees, or equivalent controlling body) of the hospital organization; (2) a committee of, or other party authorized by, the governing body of the hospital organization, to the extent permitted under state law; or (3) in the case of a hospital facility that has its own governing body and is recognized as an entity under state law but is a disregarded entity for federal tax purposes, the governing body of that hospital facility, or a committee of, or other party authorized by, that governing body to the extent permitted under state law.

Because the definition of an ''authorized body'' of a hospital facility that adopts a CHNA report or implementation strategy required under section 501(r)(3) should be the same as the definition of an ''authorized body'' for purposes of section 501(r)(4), the term ''authorized body of a hospital facility'' is defined in § 1.501(r)–1 of these proposed regulations so that it may apply for purposes of both the section 501(r)(3) and the section 501(r)(4) requirements.

2. Failures To Satisfy the Requirements of Section 501(r)

a. Minor and Inadvertent Omissions and Errors

Numerous commenters to Notice 2010–39 requested guidance on the consequences of failing to meet one or more of the requirements of section 501(r). In addition, commenters have noted that the guidance released so far on section 501(r) (in Notice 2011–52 and the 2012 proposed regulations) has proposed multiple specific requirements, and that hospitals, as large complex institutions, may experience minor and inadvertent compliance failures notwithstanding their good faith efforts to comply with the requirements. Commenters representing hospitals expressed the view that a failure to meet a section 501(r) requirement should only result in adverse consequences for a hospital organization if the failure is a substantial one. The Treasury Department and the IRS received similar informal comments from patient advocates. Commenters also recommended that no adverse consequences should result from a hospital organization's failure if the organization corrects the failure, with many of these commenters specifically suggesting that such corrections be required to be made ''by the end of the fiscal year being reported.''

The Treasury Department and the IRS recognize that minor and inadvertent errors may occur even in circumstances in which a hospital facility has practices and procedures in place that are reasonably designed to facilitate overall compliance with section 501(r) and has implemented safeguards reasonably calculated to prevent errors. Therefore, these proposed regulations provide that a hospital facility's omission of required

information from a policy or report described in § 1.501(r)–3 or § 1.501(r)–4, or error with respect to the implementation or operational requirements described in § 1.501(r)–3 through § 1.501(r)–6, will not be considered a failure to meet a requirement of section 501(r) if the omission or error was minor, inadvertent, and due to reasonable cause, and the hospital facility corrects such omission or error as promptly after discovery as is reasonable given the nature of the omission or error.

b. Excusing Certain Failures if a Hospital Facility Corrects and Makes Disclosure

With respect to omissions or errors that rise above the level of minor and inadvertent, the Treasury Department and the IRS recognize that a hospital facility's prompt discovery and correction of such omissions or errors is in the best interests of patients and that requiring hospital facilities to report such omissions or errors and disclose how such omissions or errors were corrected (for example, on the Form 990) would achieve transparency, which is an important objective of section 501(r). Increased transparency, in turn, will permit organizations concerned with community health needs to use this information to promote adoption of practices and procedures that advance the goals of the section 501(r) requirements and encourage promulgation of best practices. To provide an incentive for hospital facilities to take steps not only to avoid errors but to correct and provide disclosure when they occur, the Treasury Department and the IRS will issue a revenue procedure, notice, or other guidance published in the Internal Revenue Bulletin which will provide that a hospital facility's failure to meet one or more of the requirements described in § 1.501(r)–3 through § 1.501(r)–6 that is neither willful nor egregious will be excused if the hospital facility corrects and provides disclosure in accordance with the rules set forth in the guidance. The Treasury Department and the IRS anticipate that this guidance will provide that correction and disclosure should be reasonable and appropriate for the failure at issue.

For purposes of this provision, willful is to be interpreted consistent with the meaning of that term in the context of civil penalties, which would include a failure due to gross negligence, reckless disregard, or willful neglect. Furthermore, correction and disclosure will not create a presumption that the failure was neither willful nor egregious.

The Treasury Department and the IRS intend to issue the guidance regarding correction and disclosure in proposed form in order to provide an opportunity to comment on the procedures described therein.

c. Facts and Circumstances Considered in Determining Whether To Revoke 501(c)(3) Status

Section 501(r)(1) provides that a hospital organization will not be treated as described in section 501(c)(3) unless it meets the requirements of section 501(r). These proposed regulations interpret this language as giving the IRS the authority to revoke a hospital organization's section 501(c)(3) status if the organization fails to meet one or more requirements of section 501(r). However, the Treasury Department and the IRS agree with commenters that the IRS should consider the relative size, scope, nature, and significance of any failures to meet the section 501(r) requirements, as well as the reasons for such failures and whether the same type of failures have previously occurred, when determining whether revocation of section 501(c)(3) status is warranted. In addition, the Treasury Department and the IRS consider it desirable that these proposed regulations provide incentives for a hospital facility to establish and routinely follow practices and procedures reasonably designed to promote and facilitate overall compliance with the section 501(r) requirements and identify any problems that arise and the reasons for their occurrence. Hospital facilities should also have incentives to correct any section 501(r) failures as promptly after discovery as is reasonable given the nature of the failure and implement safeguards reasonably calculated to prevent similar failures from occurring in the future. Accordingly, these proposed regulations provide that the IRS will consider all of these facts and circumstances in determining whether to continue to recognize the section 501(c)(3) status of a hospital organization that fails to meet one or more requirements of section 501(r). In general, the Treasury Department and the IRS expect that application of these facts and circumstances will ordinarily result in revocation of the section 501(c)(3) status of a hospital organization if the organization's failures to meet the requirements of section 501(r) are willful or egregious.

d. Taxation of Noncompliant Hospital Facilities

A number of commenters recommended that if a hospital organization fails to meet a section 501(r) requirement with respect to a particular hospital facility it operates, only that hospital facility should be treated as not described in section 501(c)(3), and the facility's failure should not negate the tax exemption of the hospital organization as a whole. A few commenters recommended that if a hospital organization ceases to qualify as an organization described in section 501(c)(3) with respect to a particular hospital facility but continues to qualify as an organization described in section 501(c)(3) overall, then any net income derived from the disqualified facility should be subject to the unrelated business income tax under section 511.

Section 501(r)(2)(B)(ii) provides that a hospital organization operating more than one hospital facility shall not be treated as described in section 501(c)(3) with respect to any such hospital facility for which the requirements of section 501(r)(1) are not separately met (a ''noncompliant hospital facility''). Status under section 501(c)(3) is determined at the organizational level, and treating an organization as not described in section 501(c)(3) ''with respect to'' a particular hospital facility it operates (or a particular branch, division, or activity of the organization) has no generally recognized meaning under the provisions of the Code governing tax-exempt organizations. Notwithstanding this fact, the language in section 501(r)(2)(B)(ii) suggests that a particular noncompliant hospital facility operated by a hospital organization with more than one facility may be treated as not described in section 501(c)(3) without affecting the section 501(c)(3) status of the hospital organization. A noncompliant hospital facility that is treated as not described in section 501(c)(3), but that is owned and operated by a hospital organization that continues to be described in section 501(c)(3), cannot be described in another subsection of 501(c) (such as section 501(c)(4)), since the plain language of section 501(c) makes clear that only organizations (not facilities, branches, divisions, or other components of organizations) can be described in any one subsection of 501(c). Thus, these proposed regulations interpret section 501(r)(2)(B)(ii) to mean that a hospital organization that is not treated as described in section 501(c)(3) ''with respect to'' a particular noncompliant hospital facility ceases to be exempt from taxation under section 501(a) with respect to that facility, even while the hospital organization as a whole (with respect to its other hospital facilities and activities) continues to be otherwise exempt from taxation under

section 501(a) because it is described in section 501(c)(3).

Accordingly, these proposed regulations provide that if a hospital organization operating more than one hospital facility fails to meet one or more of the requirements of section 501(r) separately with respect to a hospital facility during a taxable year but continues to be recognized as described in section 501(c)(3), the income derived from the noncompliant hospital facility during that taxable year will be subject to tax computed as provided in section 11 (or as provided in section 1(e) if the hospital organization is a trust described in section 511(b)(2)). To maintain consistency with the treatment of organizations operating a single hospital facility, this tax will apply only if the hospital organization would not continue to be described in section 501(c)(3) based on the facts and circumstances described in section 2.c of this preamble if the noncompliant hospital facility were the only hospital facility that the organization operated. This tax would not apply in the event of minor and inadvertent omissions or errors described in section 2.a of this preamble or of failures that are excused in accordance with the guidance described in section 2.b of this preamble.

In applying the tax, the income derived from a noncompliant hospital facility during a taxable year will be the gross income derived from that hospital facility during the taxable year, less the deductions allowed by chapter 1 of the Code that are directly connected to the operation of that hospital facility during the taxable year. These proposed regulations provide that this computation will exclude any gross income and deductions already taken into account in computing any UBTI described in section 512 derived from the facility during the taxable year.

To be directly connected with the operation of a noncompliant hospital facility, these proposed regulations provide that an item of deduction must have proximate and primary relationship to the operation of the hospital facility. Expenses, depreciation, and similar items attributable solely to the operation of a hospital facility are proximately and primarily related to such operation, and therefore qualify for deduction to the extent that they meet the requirements of section 162, section 167, or other relevant provisions of the Code. These proposed regulations further provide that where expenses, depreciation, and similar items are attributable to more than one hospital facility operated by the hospital organization (and/or to activities of the hospital organization unrelated to the operation of hospital facilities), such items shall be allocated between the hospital facilities (and/or other activities) on a reasonable basis.

In addition, these proposed regulations provide the gross income and allowed deductions of a noncompliant hospital facility may not be aggregated with the gross income and allowed deductions of the hospital organization's other noncompliant hospital facilities or its unrelated trade or business activities described in section 513. Thus, a hospital organization operating more than one noncompliant hospital facility that is subject to the facility-level tax must compute each facility's taxable income separately and may not use net operating losses from one noncompliant hospital facility to offset taxable income derived from another noncompliant hospital facility. Similarly, a hospital organization may not use net operating losses from a noncompliant hospital facility to offset any UBTI derived from the organization's unrelated trade or business activities.

A number of commenters expressed concern that interest on bonds issued as qualified 501(c)(3) bonds to finance a hospital facility will become taxable if the facility fails one or more requirements of section 501(r). These proposed regulations make clear that if a hospital organization operating a noncompliant hospital facility continues to be recognized as described in section 501(c)(3) and otherwise exempt from tax under section 501(a), the fact that a facility-level tax is imposed as a result of the facility's failure to comply with section 501(r) will not itself cause the interest on such bonds to be taxable.

Finally, these proposed regulations make clear that the facility-level tax described in this section 2.d of the preamble will be reported on the Form 990–T.

3. Community Health Needs Assessments

Consistent with section 501(r)(3)(A), these proposed regulations provide that a hospital organization meets the requirements of section 501(r)(3) in any taxable year with respect to a hospital facility it operates only if the hospital facility has conducted a CHNA in such taxable year or in either of the two immediately preceding taxable years and an authorized body of the hospital facility has adopted an implementation strategy to meet the community health needs identified through the CHNA by the end of the taxable year in which the hospital facility conducts the CHNA. In general, these proposed regulations are consistent with the anticipated rules described in Notice 2011–52, with certain modifications intended to be responsive to the more than 80 comments received on Notice 2011–52.

a. Conducting a Community Health Needs Assessment

In conducting a CHNA, these proposed regulations provide that a hospital facility must define the community it serves and assess the health needs of that community. In assessing the community's health needs, the hospital facility must, consistent with section 501(r)(3)(B)(i), take into account input from persons who represent the broad interests of its community, including those with special knowledge of or expertise in public health. The hospital facility must also document the CHNA in a written report (''CHNA report'') that is adopted for the hospital facility by an authorized body of the hospital facility. Finally, consistent with section 501(r)(3)(B)(ii), the hospital facility must make the CHNA report widely available to the public. These proposed regulations provide that a CHNA is considered ''conducted'' on the date the hospital facility has completed all of these steps. Because a hospital facility must make a CHNA report widely available to the public continuously for a number of years (as discussed in section 3.a.vi of this preamble), these proposed regulations clarify that a hospital facility is considered to have completed the step of making the CHNA report widely available to the public on the date it first makes the CHNA report widely available to the public.

i. Community Served by the Hospital Facility

Notice 2011–52 stated the intention of the Treasury Department and the IRS to allow a hospital facility to take into account all of the relevant facts and circumstances in defining the community it serves. Notice 2011–52 noted that, generally, the Treasury Department and the IRS would expect a hospital facility's community to be defined geographically but that, in some cases, the definition might also take into account target populations served or specialized functions. Notwithstanding this generally flexible approach to defining community, Notice 2011–52 stated that a community could not be defined in a manner that circumvented the requirement to assess the health needs of the hospital facility's community by excluding, for example, medically underserved populations,

low-income persons, minority groups, or those with chronic disease needs. Finally, Notice 2011–52 requested comments on the relative merits of different geographically-based definitions of community and, more specifically, on whether future guidance should define the geographic community of a hospital facility as the Metropolitan Statistical Area (MSA) or Micropolitan Statistical Area (μSA) in which the facility is located or, if the hospital facility is a rural facility not located in a MSA or μSA, as the county in which the facility is located.

Many commenters supported the facts-and-circumstances approach to defining a hospital facility's community outlined in Notice 2011–52 and recommended against a definition based on specified geographic boundaries. These commenters noted that each hospital facility is in the best position to determine its community and that requiring the community to be defined as a specific geographic area may not be appropriate or correspond to the actual populations served, especially in the case of specialized and regional hospitals. These commenters also recommended against defining the community served by a hospital facility as the MSA, μSA, or county in which the facility is located, noting that such areas or politically-defined jurisdictions are often unrelated to hospital service areas.

Other commenters recommended a geographic definition of community, but requested one that would be flexible in the method of definition (for example, not restricted to specific political jurisdictions). A few commenters went further and stated that the geographic definition of community should include the political jurisdiction in which the hospital facility is located or where the hospital facility is an essential provider. These commenters recommended against definitions of community based on the demographics or residence of the hospital facility's specific patient populations, noting that a hospital facility's current patient population does not necessarily reflect the broader community.

Consistent with Notice 2011–52, these proposed regulations provide a hospital facility with the flexibility to take into account all of the relevant facts and circumstances in defining the community it serves, including the geographic area served by the hospital facility, target populations served (for example, children, women, or the aged), and principal functions (for example, focus on a particular specialty area or targeted disease). These proposed regulations also clarify that a hospital facility may define its community to include populations in addition to its patient populations and geographic areas outside of those in which its patient populations reside. For example, a hospital facility collaborating with other hospital facilities in its MSA in conducting a CHNA may define its community as the entire MSA in which all of the collaborating hospital facilities are located, even if the hospital facility itself only generally serves and draws its patients from a portion of that MSA.

While desiring to give a hospital facility the flexibility it needs to define its community served in a manner appropriate to its specific facts and circumstances, the Treasury Department and the IRS continue to share the interest expressed by some commenters in ensuring that hospital facilities assess and address the needs of medically underserved, low-income, and minority populations in the areas they serve. Thus, similar to the restriction included in Notice 2011–52, these proposed regulations provide that a hospital facility may not define its community in a way that excludes medically underserved, low-income, or minority populations who are part of its patient populations, live in geographic areas in which its patient populations reside (unless they are not part of the hospital facility's target populations or affected by its principal functions), or otherwise should be included based on the method used by the hospital facility to define its community. These proposed regulations clarify that medically underserved populations include populations experiencing health disparities or at risk of not receiving adequate medical care as a result of being uninsured or underinsured or due to geographic, language, financial, or other barriers. (For reasons discussed in section 3.a.iii.B of this preamble, these proposed regulations do not list those with chronic disease needs as a separate category of persons that must not be excluded.) Finally, if a hospital facility uses a method of defining its community that takes into account patient populations, these proposed regulations require the hospital facility to treat as patients all individuals who receive care from the hospital facility, without regard to whether (or how much) they or their insurers pay for the care received or whether they are eligible for financial assistance.

ii. Assessing Community Health Needs

These proposed regulations provide that in order to ''assess'' the health needs of the community it serves, a hospital facility must identify significant health needs of the community, prioritize those health needs, and identify potential measures and resources (such as programs, organizations, and facilities in the community) available to address the health needs. For these purposes, health needs include requisites for the improvement or maintenance of health status in both the community at large and in particular parts of the community (such as particular neighborhoods or populations experiencing health disparities). Requisites for the improvement or maintenance of health status in a community may include improving access to care by removing financial and other barriers to care, such as a lack of information regarding sources of insurance designed to benefit vulnerable populations.

Notice 2011–52 stated the intention of the Treasury Department and the IRS to require a hospital facility to prioritize all of the community health needs identified through the CHNA. A few commenters suggested that only the most significant of the likely extensive list of community health needs identified through a CHNA should have to be prioritized. These proposed regulations respond to this comment by clarifying that a CHNA need only identify significant health needs and need only prioritize, and otherwise assess, those significant health needs identified. A hospital facility may determine whether a health need is significant based on all of the facts and circumstances present in the community it serves.

A few commenters asked for additional guidance regarding how a CHNA should prioritize community health needs. These proposed regulations do not require a hospital facility to use any particular methods or criteria in prioritizing health needs. They do, however, list as possible examples of prioritization criteria the burden, scope, severity, or urgency of the health need; the estimated feasibility and effectiveness of possible interventions; the health disparities associated with the need; and/or the importance the community places on addressing the need. This list of possible prioritization criteria is not intended to be exhaustive, and a hospital facility may use any criteria it deems appropriate.

iii. Persons Representing the Broad Interests of the Community

In assessing the health needs of the community it serves, these proposed regulations require a hospital facility to (consistent with section 501(r)(3)(B)(i)) take into account input from persons

who represent the broad interests of the community served by the hospital facility, including those with special knowledge of or expertise in public health. Specifically, these proposed regulations require a hospital facility to take into account input from, at a minimum: (1) At least one state, local, tribal, or regional governmental public health department (or equivalent department or agency) with knowledge, information, or expertise relevant to the health needs of the community; (2) members of medically underserved, low-income, and minority populations in the community, or individuals or organizations serving or representing the interests of such populations; and (3) written comments received on the hospital facility's most recently conducted CHNA and most recently adopted implementation strategy.

Notice 2011–52 stated that the Treasury Department and the IRS intended to require a CHNA to take into account input from, at a minimum: (1) Persons with special knowledge of or expertise in public health; (2) federal, tribal, regional, state, or local health or other departments or agencies, with current data or other information relevant to the health needs of the community served by the hospital facility; and (3) leaders, representatives, or members of medically underserved, low-income, and minority populations, and populations with chronic disease needs, in the community served by the hospital facility.

A. Governmental Public Health Departments

With respect to the requirement described in Notice 2011–52 to take into account input from federal, tribal, regional, state, or local health or other departments, many commenters urged that a hospital facility should be able to choose the level and type of governmental public health department from which it seeks input, noting that not every local jurisdiction has a local public health department. On the other hand, a number of public health organizations suggested that these proposed regulations should require a hospital facility to consult with the state public health department in the state where the hospital facility is licensed and/or the local public health department in the local jurisdiction where the hospital facility is located. These organizations noted that such departments can play a critically important role in coordinating CHNA efforts and provide expertise in CHNA planning and execution, access to existing health data, and knowledge of local conditions, needs, and resources.

These proposed regulations preserve the flexibility in Notice 2011–52 of allowing a hospital facility to choose the jurisdictional level of government (for example, state, local, tribal, or regional) that it feels is most appropriate for its CHNA. These proposed regulations do not require a hospital facility to seek input from a local public health department, in particular, in recognition of some commenters' observation that not all jurisdictions will have local public health departments available to participate in the CHNA process. However, in recognition of the planning and subject-matter expertise that public health departments can offer to the CHNA process, a hospital facility is required to seek input from a public health department (or equivalent department or agency) in particular, rather than any governmental departments with current data or other information relevant to the health needs of the community (as described in Notice 2011–52). Such input could include input from the state public health official or any local public health official.

In addition, given commenters' emphasis on the importance of input from public health departments at the state or local level, these proposed regulations require a hospital facility to seek input from a public health department at a state or local, not a federal, level. Because a governmental public health department presumably has special knowledge of or expertise in public health, requiring input from a public health department eliminates the need for a separate requirement to consult with a person with special knowledge of or expertise in public health (as provided in Notice 2011–52).

B. Medically Underserved, Low-Income, and Minority Populations

Commenters generally supported the purpose behind the requirement to take into account input from medically underserved, low-income, and minority populations in the community but asked for clarification on who may be considered ''leaders'' or ''representatives'' of such populations. One commenter noted that the term ''chronic disease needs'' is broad and could potentially require a hospital facility to seek input from a large number of individuals in order to address every chronic disease in its community.

These proposed regulations maintain the requirement to take into account input from medically underserved, low-income, and minority populations in the community served by the hospital facility but respond to comments by clarifying and simplifying the approach taken in Notice 2011–52. To address the numerous comments expressing confusion over the terms ''leaders'' and ''representatives'' of such populations, these proposed regulations clarify that a hospital facility may seek input either directly from members of medically underserved, low-income, and minority populations in the community (for example, in the form of meetings, focus groups, surveys, or interviews) or from individuals or organizations serving or representing the interests of those populations. To address the concern with requiring input related to every chronic disease in a community, these proposed regulations do not refer to chronic disease needs in particular but rather define ''medically underserved populations'' in a manner that focuses on disparities in coverage, access, and other barriers to care for persons with health needs that may include, but are not limited to, chronic diseases.

C. Written Comments

A few commenters recommended an input requirement not contained in Notice 2011–52: a requirement that a hospital facility take into account public input and comments on a draft version of its CHNA report before the report is finalized. These commenters noted the importance of a public comment process for ensuring that the CHNA accurately reflects the community's views and priorities and adequately analyzes available data.

These proposed regulations do not adopt the specific recommendations to require hospital facilities to make a draft copy of a CHNA report available for public comment due to the complexity of the additional timeframes and procedures such a process would require. However, the Treasury Department and the IRS recognize the value of providing a mechanism for public feedback on CHNA reports and their related implementation strategies. Therefore, these proposed regulations respond to these comments by requiring a hospital facility to consider written comments received from the public on the hospital facility's most recently conducted CHNA and most recently adopted implementation strategy. (As discussed in section 4 of this preamble, the public will be able to review a hospital facility's most recently adopted implementation strategy because it will either be attached to the Form 990 of the hospital organization that operates it or made widely available on a Web site.) Because a new CHNA must be conducted and an implementation strategy adopted at least once every three years, this requirement establishes

the same sort of continual feedback on CHNA reports suggested by commenters, albeit over a longer period of time. It is anticipated that this opportunity for feedback on CHNA reports and implementation strategies will result in a meaningful exchange over time and that the longer timeframe will give the public sufficient time to provide comments and hospital facilities sufficient time to consider the public's comments and take the comments into account when conducting their next CHNA. In addition, as discussed in section 3.a.vi of this preamble, to help facilitate the option of posting a draft CHNA report for public review and comment, these proposed regulations provide that the posting of draft CHNA reports will not trigger the start of a hospital facility's next three-year CHNA cycle.

D. Input on Financial and Other Barriers and From Other Sources

In addition, some commenters recommended that a hospital facility should be required to integrate evaluations of financial assistance policies and procedures and the need for uncompensated care into its CHNA. The Treasury Department and the IRS recognize that the need to improve access to care by removing financial barriers can be among the significant health needs assessed in a CHNA. Accordingly, these proposed regulations provide that input from persons representing the broad interests of the community includes, but is not limited to, input on any financial and other barriers to access to care in the community.

Finally, similar to Notice 2011–52, these proposed regulations provide that a hospital facility may take into account input from a broad range of persons located in or serving its community who may have special knowledge of or expertise in public health, including, but not limited to, health care consumers and consumer advocates, nonprofit and community-based organizations, academic experts, local government officials, local school districts, health care providers and community health centers, health insurance and managed care organizations, private businesses, and labor and workforce representatives. As discussed in section 3.a.vi of this preamble, one way for a hospital facility to take into account input from such a broad range of persons is to pursue the option of posting on its Web site a draft CHNA report for public review and comment. The Treasury Department and the IRS believe a CHNA with broad input from the community can increase the likelihood of well-targeted initiatives that address the needs of communities and improve the health of residents.

iv. Documentation of a CHNA

Similar to the documentation rule described in Notice 2011–52, these proposed regulations provide that a hospital facility must document its CHNA in a CHNA report that is adopted by an authorized body of the hospital facility and includes: (1) A definition of the community served by the hospital facility and a description of how the community was determined; (2) a description of the process and methods used to conduct the CHNA; (3) a description of how the hospital facility took into account input from persons who represent the broad interests of the community it serves; (4) a prioritized description of the significant health needs of the community identified through the CHNA, along with a description of the process and criteria used in identifying certain health needs as significant and prioritizing such significant health needs; and (5) a description of potential measures and resources identified through the CHNA to address the significant health needs.

Like Notice 2011–52, the proposed regulations provide more detail about two of these required elements of the CHNA report: the description of the process and methods used to conduct the CHNA and the description of how the hospital facility took into account input from persons who represent the broad interests of the community. However, in response to comments about the need for greater flexibility, these proposed regulations provide that a hospital facility's CHNA report ''will be considered to'' describe each of these elements if it contains certain information instead of prescribing a single method of meeting the requirement.

A. Description of Process and Methods

These proposed regulations provide that a hospital facility's CHNA report will be considered to describe the process and methods used to conduct the CHNA if the CHNA report: (1) describes the data and other information used in the assessment, as well as the methods of collecting and analyzing this data and information, and (2) identifies any parties with whom the hospital facility collaborated, or with whom it contracted for assistance, in conducting the CHNA.

B. Description of Community Input

In describing how the hospital facility took into account input from persons who represent the broad interests of the community it serves, Notice 2011–52 stated that a hospital facility would have to describe when and how the organization consulted with such persons. A number of commenters sought clarification that a general summary of ''when and how'' would be sufficient. Specifically, some of these commenters noted that a detailed account of each instance of feedback could be quite burdensome and may create the impression that less formal interactions with community members are insufficient or unworthy of consideration or hinder the free flow of information.

In response to these comments, these proposed regulations clarify that the CHNA report may summarize, in general terms, how and over what time period input was provided (for example, whether through meetings, focus groups, interviews, surveys, or written comments and between what dates) and need not provide a detailed description of each instance of feedback. These proposed regulations also clarify that the CHNA report may contain a general summary of the input received. Thus, for example, a hospital facility may describe a series of town hall meetings by noting that four meetings were held over a three-month period and generally summarizing the input received, without necessarily having to provide the specific dates of each meeting, a list of attendees, or minutes of the discussion.

Notice 2011–52 stated that a hospital facility taking into account input from an organization would be required to identify in the CHNA report not only the organization but also the name and title of at least one individual in the organization with whom the hospital facility consulted. Commenters, however, were generally opposed to inclusion in the publicly available CHNA report of the names and roles of private individuals who gave input into the CHNA process, noting that the information may not add much value to the overall CHNA but could raise privacy concerns and deter individuals from providing input. In response to these comments, these proposed regulations do not specifically require the CHNA report to contain the names or titles of any individuals contacted within an organization. In addition, the proposed regulations specify that a CHNA report does not need to name or otherwise individually identify any individuals participating in community forums, focus groups, survey samples, or similar groups.

However, the Treasury Department and the IRS continue to believe that a

CHNA report should identify the organizations that provided input into the CHNA and summarize the nature and extent of that input. In addition, a CHNA report should describe the medically underserved, low-income, or minority populations being represented by the organizations or individuals providing input. Accordingly, these proposed regulations provide that a hospital facility's CHNA report will be considered to describe how the hospital facility took into account input if the CHNA report: (1) Summarizes, in general terms, the input provided and how and over what time period such input was provided; (2) provides the names of organizations providing input and summarizes the nature and extent of the organization's input; and (3) describes the medically underserved, low-income, or minority populations being represented by organizations or individuals providing input.

The Treasury Department and the IRS request comments regarding whether these proposed rules provide for sufficient disclosure regarding the community input into a CHNA report, or whether the CHNA report should be required to provide any other information regarding input provided, in order to ensure transparency in the CHNA process.

C. Description of Prioritization of the Community's Health Needs and of Potential Measures and Identified Resources to Address Such Needs

With respect to the requirement in Notice 2011–52 to describe the existing health care facilities and other resources within the community available to meet the health needs identified through the CHNA, many commenters asked that the description of these resources be limited to known or available facilities and resources. These commenters argued that a community-wide inventory of health care resources is not the responsibility of any one hospital facility, but rather a task more appropriate to public health departments. Accordingly, these proposed regulations limit the description of resources available to address health needs to those known or identified in the course of conducting the CHNA.

Additional commenters remarked that both the prioritization of health needs and a description of resources available to meet the health needs identified through the CHNA are more appropriate in an implementation strategy than in a CHNA report. On the other hand, other commenters noted the importance of community input in the overall CHNA process and sought an opportunity to provide input on potential interventions and programs that may be included in a hospital facility's implementation strategy. In fact, such commenters asked that the implementation strategy, in addition to the CHNA, be subject to public input and made widely available to the public.

The Treasury Department and the IRS recognize that conducting a CHNA and developing an implementation strategy are part of one fluid process, with no definite point at which the CHNA ends and the implementation strategy begins. Prioritizing health needs and identifying potential measures and resources to address health needs, for example, could reasonably be interpreted as part of ''assessing'' those health needs or, alternatively, as the first step in devising a strategy to meet those needs. Accordingly, these proposed regulations respond to commenters' requests for enhanced transparency and an opportunity for community input by requiring items that could reasonably be included as part of either the CHNA or the implementation strategy to be described in the CHNA report. Thus, these proposed regulations require the CHNA report to include a prioritized description of the significant health needs of the community identified through the CHNA, along with a description of the process and criteria used in prioritizing these health needs. These proposed regulations also require the CHNA report to include a description of the potential measures and resources identified through the CHNA to address the significant health needs.

v. Collaboration on CHNA Reports

Notice 2011–52 stated that the Treasury Department and the IRS intend to allow a hospital organization to conduct a CHNA in collaboration with other organizations, including related organizations, other hospital organizations, for-profit and government hospitals, and public health and other departments of state and local governments. However, even in cases where collaboration between hospitals occurs, Notice 2011–52 stated that the Treasury Department and the IRS intended to require each hospital facility to document its CHNA in a separate written report. Many commenters recommended that when several hospital facilities within the same defined community work collaboratively on a CHNA, they should be able to issue a joint CHNA report or separate CHNA reports that are substantively identical. These commenters argued that joint reporting would encourage collaboration, reduce redundancy and expense, and provide a more coherent picture of the community's health needs. Some of these commenters suggested that the joint CHNA report could be required to contain different sections for each particular hospital facility. On the other hand, other commenters recommended retaining the requirement for separate CHNA reports, noting that facility-level reporting ensures that information for each hospital facility is clearly presented and easily accessible.

In balancing these concerns, these proposed regulations provide, generally, that every hospital facility must document its CHNA in a separate CHNA report. However, these proposed regulations provide that if a hospital facility is collaborating with other facilities and organizations in conducting its CHNA or is basing its CHNA, in part, on a CHNA for all or part of its community conducted by another organization, portions of the hospital facility's CHNA report may be substantively identical to the CHNA report of a collaborating hospital facility or the other organization conducting a CHNA, if appropriate under the facts and circumstances. For example, if a hospital facility conducts a survey of the health needs of residents of homeless shelters located in the community in collaboration with other hospital facilities, the description of that survey in the hospital facility's CHNA report may be identical to the description contained in the CHNA reports for the other collaborating hospital facilities. Similarly, if the state or local public health department with jurisdiction over the community served by the hospital facility conducts an inventory of community health improvement resources available in that community, the hospital facility may include that inventory in its CHNA report.

These proposed regulations also provide an exception to the general requirement of separate CHNA reports: namely, if a hospital facility collaborates with other hospital facilities in conducting its CHNA, all of the collaborating hospital facilities may produce a joint CHNA report as long as all of the facilities define their community to be the same and conduct a joint CHNA process. In addition, the joint CHNA report must clearly identify each hospital facility to which it applies and an authorized body of each collaborating hospital facility must adopt the joint CHNA report as its own.

Thus, for example, if a hospital facility collaborates with nine other hospital facilities that are all located in and serving a particular MSA, all ten hospital facilities define their

community as constituting the entire MSA, and all ten hospital facilities conduct a joint CHNA process, the ten hospital facilities may prepare a joint CHNA report that identifies all of the collaborating hospital facilities by name. Under these proposed regulations, such a joint CHNA report would satisfy the requirement to document the CHNA in a written CHNA report for any one of the collaborating hospital facilities as long as the joint CHNA report is adopted by an authorized body of the hospital facility.

vi. Making the CHNA Report Widely Available to the Public

Consistent with Notice 2011–52, these proposed regulations provide that in order to make its CHNA report widely available to the public, a hospital facility must post the CHNA report on the hospital facility's Web site or, if the hospital facility does not have its own Web site separate from the hospital organization that operates it, on the hospital organization's Web site. Alternatively, the hospital facility may post the CHNA report on a Web site established and maintained by another entity as long as either the hospital facility or hospital organization's Web site (if the facility or organization has a Web site) provides a link to the Web page on which the CHNA report is posted, along with clear instructions for accessing the report on that Web site. In addition, the hospital facility must ensure that individuals with access to the Internet can access, download, view, and print a hard copy of the CHNA report without requiring special computer hardware or software (other than software that is readily available to members of the public without payment of any fee) and without payment of a fee to the hospital facility, hospital organization, or other entity maintaining the Web site. Finally, the hospital facility must provide individuals who ask how to access a copy of the CHNA report online with the direct Web site address, or URL, of the Web page on which the document is posted.

Commenters generally supported the requirement outlined in Notice 2011–52 to make the CHNA report widely available on a Web site. Many of these commenters believed that this Web posting requirement alone was sufficient to make the CHNA report widely available to the public. Others, however, urged the Treasury Department and the IRS to expand the requirements for making a CHNA widely available to the public to require the hospital facility to provide paper copies of the CHNA report for free to any individual requesting it. Some commenters requested a requirement that the hospital facility identify strategies to inform various sectors of the community that the CHNA report is widely available on a Web site.

A few commenters also recommended expanding the requirements associated with making CHNA reports widely available on a Web site. Some commenters recommended requiring that the CHNA reports be conspicuously posted on the applicable Web site, for example by requiring a highly visible link on the Web site's homepage. Another commenter recommended requiring past, as well as current, CHNA reports to be posted, to demonstrate improvement of health care objectives over the long term. Yet another commenter recommended requiring that individuals do not need to provide personally identifiable information or create an account to access the CHNA report.

Because of the focus on increased transparency of hospital facilities in section 501(r), the Treasury Department and the IRS have adopted most of the comments seeking to enhance transparency of a hospital facility's CHNA by expanding the requirements to make the CHNA report widely available to the public. Specifically, these proposed regulations make four changes to the interim rule described in Notice 2011–52 for making the CHNA report widely available to the public. First, these proposed regulations require a complete version of the CHNA report to be ''conspicuously'' posted on a Web site, to ensure that the CHNA report can be easily located on the Web site. Second, instead of requiring the CHNA report to be posted on the Web site until the next CHNA report is posted, these proposed regulations require the CHNA report to remain on the Web site until two subsequent CHNA reports have been posted, so information on trends will be available to the public. Third, these proposed regulations add that an individual must not be required to create an account or otherwise be required to provide personally identifiable information in order to access the CHNA report on a Web site. Fourth, these proposed regulations add a requirement that a hospital facility must make a paper copy of its CHNA report available for public inspection without charge at the hospital facility at least until the date the hospital facility has made available for public inspection, without charge, a paper copy of its two subsequent CHNAs.

Because the requirement to make a document ''widely available on a Web site'' applies not only to a hospital facility's CHNA reports but also, under the 2012 proposed regulations, to its financial assistance policy and related documents, the term ''widely available on a Web site'' is defined in the definitions section of these proposed regulations and will apply to both rules.

Finally, to facilitate the sharing of draft versions of the CHNA report for comment as requested by some commenters, these proposed regulations provide that a hospital facility will not be considered to have made the CHNA report widely available to the public for purposes of determining the date on which the hospital facility has conducted the CHNA if it makes widely available on a Web site (and/or for public inspection) a version of the CHNA report that is expressly marked as a draft on which the public may comment. Thus, a hospital facility may post a draft CHNA report for public review and comment without starting its next three-year CHNA cycle.

b. Implementation Strategies

Notice 2011–52 noted the intention of the Treasury Department and the IRS to define an ''implementation strategy'' for a hospital facility as a written plan that addresses each of the health needs identified through a CHNA for the facility. Notice 2011–52 further provided that an implementation strategy would ''address'' a health need identified through a CHNA if the written plan either: (1) describes how the hospital facility plans to meet the health need, or (2) identifies the health need as one the hospital facility does not intend to meet and explains why the hospital facility does not intend to meet the health need.

A number of commenters asked that the implementation strategy be required to address only significant or priority health needs identified through the CHNA. Other commenters asked if the implementation strategy could address health needs identified from a source other than the hospital facility's CHNA.

As indicated in section 3.a.ii of this preamble, these proposed regulations limit the health needs that a hospital facility must identify through its CHNA to significant health needs and the health needs covered in the implementation strategy are limited to those significant health needs identified through the CHNA. In addition, these proposed regulations do not require a hospital facility to develop a strategy or plan to address each identified significant health need. Rather, consistent with section 6033(b)(15)(A) of the Code, these proposed regulations follow the approach set forth in Notice 2011–52 and clarify that a hospital facility's implementation strategy must,

with respect to each significant health need identified through the CHNA, either: (1) describe how the hospital facility plans to address the health need; or (2) identify the health need as one the hospital facility does not intend to address and explain why the hospital facility does not intend to address the health need. Accordingly, an implementation strategy may describe how the hospital facility plans to address only a few of the significant health needs identified through a CHNA, as long as it explains why it does not intend to address the other identified significant health needs for which no plan is provided.

Although an implementation strategy must address the significant health needs identified through a hospital facility's CHNA, these proposed regulations do not limit an implementation strategy to addressing only those health needs, and it may describe activities to address health needs that the hospital facility identifies in other ways.

i. Describing How a Hospital Facility Plans To Address a Significant Health Need

Commenters recommended that the implementation strategy be required to describe its intended impact on health outcomes. Some of these commenters recommended that the descriptions of intended impacts include short- and long-term measurable goals and objectives, as well as methods to evaluate the plan's effectiveness. One commenter stated that an implementation strategy should assign an economic value to each strategy or activity, and an aggregate total benefit. Others recommended requiring the implementation strategy to include a mechanism to receive ongoing community feedback.

In describing how a hospital facility plans to address a significant health need identified through the CHNA, these proposed regulations adopt some of the commenters' recommendations by requiring the implementation strategy to describe, in addition to the actions the hospital facility intends to take to address the health need, the anticipated impact of these actions and the plan to evaluate such impact. For example, a hospital facility's CHNA may identify as significant health needs financial or other barriers to care in the community, such as high rates of financial need or large numbers of uninsured individuals and families. Its implementation strategy could describe a program to decrease the impact of these barriers, such as by expanding its financial assistance program or helping uninsured individuals and families learn about and enroll in sources of insurance such as Medicare, Medicaid, Children's Health Insurance Program (CHIP), and the new Health Insurance Marketplaces (also known as the Exchanges); state how it anticipates its program will reduce these barriers to care; and identify the data sources it will use to track the program's impact on the barriers.

These proposed regulations also require the implementation strategy to identify the programs and resources the hospital facility plans to commit to address the health need. Finally, the implementation strategy must describe any planned collaboration between the hospital facility and other facilities or organizations in addressing the health need.

While these proposed regulations do not require the implementation strategy itself to include any particular mechanism for community input, they do provide that a hospital facility must establish an ongoing feedback mechanism by requiring a hospital facility, in conducting a CHNA, to take into account written comments received on its most recently adopted implementation strategy, as described in section 3.a.iii.C of this preamble.

ii. Describing Why a Hospital Facility Is Not Addressing a Significant Health Need

Several commenters sought clarification regarding the level of detail required in the implementation strategy's explanation of why the hospital facility does not intend to address a significant health need. Some of these commenters stated that an explanation of the prioritization strategy together with comments noting that another facility or organization is addressing the health need should be sufficient.

These proposed regulations clarify that a brief explanation of why a hospital facility does not intend to address the significant health need is sufficient. Some possible examples of reasons a hospital facility might offer for not addressing a health need, include, but are not limited to, resource constraints, relative lack of expertise or competency to effectively address the need, a relatively low priority assigned to the need, a lack of identified effective interventions to address the need, and/or the fact that the need is being addressed by other facilities or organizations in the community. This list of possible reasons is not intended to be exhaustive, and a hospital facility may provide whatever reasons reflect its particular facts and circumstances.

iii. Joint Implementation Strategies

Notice 2011–52 noted that the Treasury Department and the IRS intended to allow hospital facilities to collaborate with other facilities and organizations in developing an implementation strategy but to still require each hospital facility to separately document its implementation strategy. Some commenters requested that hospital facilities conducting a joint CHNA should be permitted to adopt a joint implementation strategy while other commenters recommended retaining the requirement for separate implementation strategies, with each side advancing arguments similar to those advanced for and against joint CHNA reports.

In balancing these concerns, these proposed regulations state that a hospital facility may develop an implementation strategy in collaboration with other facilities and organizations. In addition, these proposed regulations provide that a hospital facility that collaborates with other facilities or organizations in developing its implementation strategy generally must document its implementation strategy in a separate written plan that is tailored to the hospital facility and takes into account its specific programs and resources.

However, these proposed regulations also provide an exception to the general requirement of separate implementation strategies: namely, a hospital facility collaborating with other hospital facilities may adopt a joint implementation strategy as long as it documents its CHNA in a joint CHNA report (as described in section 3.a.v of this preamble) and the joint implementation strategy meets three requirements. First, the joint implementation strategy must be clearly identified as applying to the hospital facility. Second, the joint implementation strategy must clearly identify the hospital facility's particular role and responsibilities in taking the actions described in the implementation strategy and the programs and resources the hospital facility plans to commit in taking those actions. Third, the joint implementation strategy must include a summary or other tool that helps the reader easily locate those portions of the joint implementation strategy that relate to the hospital facility.

iv. When the Implementation Strategy Must Be Adopted

In order to satisfy the CHNA requirements with respect to any taxable year, section 501(r)(3)(A)(ii) requires a hospital facility to adopt an

implementation strategy to meet the health needs identified through the CHNA described in section 501(r)(3)(A)(i). Consistent with this statutory language, Notice 2011–52 stated the intention of the Treasury Department and the IRS to require a hospital facility to adopt an implementation strategy to meet the health needs identified through a CHNA by the end of the same taxable year in which it conducts that CHNA. A number of commenters sought additional time to complete the implementation strategy, in part to accommodate collaborating hospital facilities with different taxable years. Most of these commenters recommended that the implementation strategy should be adopted within 12 months after completion of the CHNA or by the end of the next taxable year, rather than by the end of the same taxable year in which the CHNA is completed.

Because a hospital facility only has to conduct a CHNA once every three years and may begin the CHNA process at any time during the three-year period, a hospital facility should have ample time to complete the CHNA earlier in the third taxable year and adopt an implementation strategy by the end of that same taxable year. The flexibility afforded by a three-year cycle should also allow hospital facilities with different tax years sufficient time to collaborate. Thus, consistent with Notice 2011–52, these proposed regulations provide that an authorized body of the hospital facility must adopt the implementation strategy by the end of the same taxable year in which the hospital facility finishes conducting the CHNA (typically, by making the CHNA report widely available to the public). These proposed regulations also clarify that if a hospital facility begins working on a CHNA in one taxable year but completes the final required step for the CHNA (and hence is considered to have conducted it) in the subsequent taxable year, it is not required to adopt the implementation strategy until the taxable year in which the CHNA process is considered conducted, not the year it began. The Treasury Department and the IRS seek comments on whether this rule will materially inhibit the ability of hospital facilities with different taxable years to collaborate with each other or otherwise burden hospital facilities unnecessarily.

Notwithstanding the general rule that the implementation strategy must be adopted in the same taxable year the CHNA is considered conducted, these proposed regulations provide transition relief for the adoption of a hospital facility's implementation strategy for its first CHNA conducted after the effective date of section 501(r)(3), in recognition of the fact that certain hospital facilities may not have a full three years in which to conduct their first CHNA. This transition relief is described in section 3.d of this preamble.

c. New Hospital Facilities

Notice 2011–52 requested comments regarding when a hospital facility that is newly acquired or placed into service must conduct a CHNA. Comments received on this issue ranged from requiring such a hospital facility to conduct a CHNA within the first taxable year of acquisition or licensing to allowing the facility three taxable years following the date of acquisition or licensing. In addition, at least two commenters asked for clarification on when a for-profit hospital that converts to section 501(c)(3) status must conduct a CHNA. Additional commenters asked if a short taxable year resulting from, for example, a change in ownership, is considered a ''taxable year'' for purposes of the three-year CHNA cycle.

These proposed regulations provide that a hospital facility that is newly acquired or placed into service by a hospital organization, or that becomes newly subject to section 501(r) because the hospital organization that operates it is newly recognized as described in section 501(c)(3), must conduct a CHNA and adopt an implementation strategy to meet the community health needs identified through that CHNA by the last day of the second taxable year beginning after the date, respectively, the hospital facility is acquired or placed into service, or newly subject to section 501(r).

A short taxable year of less than twelve months is considered a taxable year for purposes of section 501(r). Thus, the taxable year in which a hospital facility is acquired or placed into service, or becomes subject to section 501(r), is a taxable year for purposes of the CHNA requirements, regardless of whether that taxable year is less than twelve months. As a result, a deadline of the last day of the second taxable year beginning after the date of acquisition, licensure, or section 501(c)(3) recognition provides these new hospital facilities with three taxable years (even if less than three full calendar years) to meet the section 501(r)(3) requirements.

d. Transition Rules

A number of commenters requested various forms of transition relief, noting the complexity of the new CHNA requirements. In particular, a few commenters asked if a CHNA conducted before the effective date of the CHNA requirements could satisfy the CHNA requirements for a taxable year beginning after the effective date (that is, for a taxable year beginning after March 23, 2012). In addition, several commenters specifically requested transition relief with respect to the first implementation strategy adopted after the effective date of the CHNA requirements. The suggestions for transition relief for the adoption of the first implementation strategy ranged from 30 to 60 days after the end of the taxable year in which the CHNA was conducted to the end of the taxable year following the taxable year in which the CHNA was conducted. In response to these comments, these proposed regulations provide transition relief that is tailored to the taxable year after March 23, 2010, in which a hospital facility conducts its first CHNA.

i. CHNA Conducted in Taxable Year Beginning Before March 23, 2012

These proposed regulations provide that a hospital facility that conducted a CHNA described in section 501(r)(3) in either of its first two taxable years beginning after March 23, 2010, does not need to meet the requirements of section 501(r)(3) again until the third taxable year following the taxable year in which the hospital facility conducted the CHNA. To qualify for this transition relief, the hospital facility must adopt an implementation strategy to meet the community health needs identified through the CHNA conducted in its first taxable year beginning after March 23, 2010 or 2011 on or before the 15th day of the fifth calendar month following the close of its first taxable year beginning after March 23, 2012. Thus, for example, if a hospital facility reporting on a calendar-year basis conducts a CHNA in 2012 and adopts an implementation strategy for that CHNA on or before May 15, 2014, it does not need to meet the section 501(r)(3) requirements again until 2015.

ii. CHNA Conducted in First Taxable Year Beginning After March 23, 2012

If a hospital facility conducts a CHNA described in section 501(r)(3) in its first taxable year beginning after March 23, 2012, these proposed regulations provide that the hospital facility will be deemed to satisfy the requirement to adopt an implementation strategy in the same taxable year the CHNA is conducted if an authorized body of the hospital facility adopts an implementation strategy to meet the community health needs identified through that CHNA on or before the

15th day of the fifth calendar month following the close of its first taxable year beginning after March 23, 2012.

4. Reporting Requirements Related to CHNAs

Notice 2011–52 stated the intention of the Treasury Department and the IRS to require a hospital organization to attach to its annual information return (Form 990) the most recently adopted implementation strategy for each of the hospital facilities it operates. A few commenters stated that, rather than require the entire implementation strategy to be attached to the Form 990, the Treasury Department and the IRS should permit a narrative summary description of the contents of its implementation strategy to be provided on the Form 990. One of these commenters noted that the implementation strategy is only required to be updated every three years, so in many instances a narrative may provide more relevant and timely information. A number of other commenters recommended requiring the implementation strategy to be made widely available to the public, rather than merely attached to the Form 990, in order to encourage greater transparency and provide an opportunity for public input and comment.

These proposed regulations allow a hospital organization either to attach to its Form 990 a copy of the most recently adopted implementation strategy for each hospital facility it operates or to provide on the Form 990 the URL(s) of the Web page(s) on which it has made each implementation strategy widely available on a Web site. An implementation strategy must describe, with respect to each significant health need identified through the CHNA, how the hospital facility plans to address the health need or why the hospital facility does not intend to address the health need. Similarly, section 6033(b)(15)(A) requires a hospital organization to furnish annually information setting forth a ''description of how the organization is addressing the needs identified in each'' CHNA and ''a description of any such needs that are not being addressed together with the reasons why such needs are not being addressed.'' Thus, the requirement in these proposed regulations to attach the implementation strategy to the Form 990, or provide on the Form 990 the URL where the implementation strategy is made widely available on a Web site, partially implements section 6033(b)(15)(A).

However, the requirement in section 6033(b)(15)(A) also encompasses an annual, up-to-date description of the actions actually taken by a hospital facility during the taxable year to address the significant health needs identified through the most recently conducted CHNA (which, presumably, will typically be steps taken during a taxable year to execute the hospital facility's most recently adopted implementation strategy). Accordingly, these proposed regulations require a hospital organization to provide annually on the Form 990 a description of the actions taken during the taxable year to address the significant health needs identified through its most recent CHNA for each hospital facility it operates or, if no actions were taken with respect to one or more of these health needs, the reason or reasons why no actions were taken.

These proposed regulations also reiterate the requirement of section 6033(b)(15)(B) that a hospital organization attach to its Form 990 a copy of its audited financial statements for the taxable year—or in the case of an organization the financial statements of which are included in consolidated financial statements with other organizations, such consolidated financial statements. The Treasury Department and the IRS request comments regarding whether hospital organizations whose financial statements are included in consolidated financial statements should be able to redact financial information about any taxable organizations that are members of the consolidated group.

Finally, consistent with section 6033(b)(10), these proposed regulations require a hospital organization to disclose the amount of the excise tax imposed on the organization under section 4959 during the taxable year for failures to meet the requirements of section 501(r)(3).

A few commenters requested clarification regarding whether government hospitals will continue to be excepted from these and other Form 990 reporting requirements under Rev. Proc. 95–48 (1995–2 C.B. 418). In Rev. Proc. 95–48, the IRS exercised its discretionary authority under section 6033(a)(3)(B) to relieve certain governmental units and affiliates of governmental units from the requirement to file a Form 990. The Affordable Care Act did not change the requirements regarding which organizations are required to file a Form 990. Accordingly, a government hospital (other than one that is described in section 509(a)(3)) that has been excused from filing a Form 990 under Rev. Proc. 95–48 or a successor revenue procedure is not required to file a Form 990. Because government hospitals described in Rev. Proc. 95–48 (other than those described in section 509(a)(3)) are relieved from the annual filing requirements under section 6033, they are also relieved from any new reporting requirements imposed on hospital organizations by these proposed regulations under section 6033, including under sections 6033(b)(10)(D) and (b)(15) and the proposed requirement to attach one or more implementation strategies to a Form 990.

5. Excise Tax on Failure to Meet CHNA Requirements

Section 4959 imposes a $50,000 excise tax on a hospital organization that fails to meet the CHNA requirements of section 501(r)(3) with respect to any taxable year.

Notice 2011–52 indicated the intent of the Treasury Department and the IRS to impose the $50,000 tax with respect to a failure by a hospital facility to satisfy section 501(r)(3) in any three-year period, making it possible for the excise tax to apply in sequential years. Notice 2011–52 provided an example of a hospital organization that reports on a calendar-year basis and operates only one hospital facility, which is subject to the $50,000 excise tax in 2013 because the hospital facility failed to conduct a CHNA in 2011, 2012, and 2013. If the hospital facility again fails to conduct a CHNA by the last day of 2014, Notice 2011–52 noted the hospital organization will again be subject to the $50,000 excise tax in 2014 for the hospital facility's failure to conduct a CHNA in 2012, 2013, and 2014. These proposed regulations include this example of the application of the section 4959 excise tax and confirm that the excise tax may be imposed for each taxable year that a hospital facility fails to meet the section 501(r)(3) requirements. These proposed regulations also make clear that the excise tax may be imposed in addition to any tax imposed on a noncompliant hospital facility as described in section 2.d of this preamble or that results from revocation of a hospital organization's section 501(c)(3) status.

In addition, Notice 2011–52 stated the intention of the Treasury Department and the IRS to apply the section 4959 excise tax separately with respect to each hospital facility's failure to meet the CHNA requirements. Thus, if a hospital organization that operates two hospital facilities fails to meet the requirements of section 501(r)(3) with respect to both facilities in any taxable year, the hospital organization will be subject to a total excise tax of $100,000

($50,000 for each hospital facility) for that taxable year.

At least one commenter argued that applying the $50,000 excise tax on a facility-by-facility basis is inconsistent with the statutory language in section 4959 that ''there is imposed on the organization a tax equal to $50,000.'' On the other hand, two commenters explicitly supported applying the section 4959 excise tax at the hospital facility level. One of these commenters expressed concern that if the $50,000 excise tax were imposed on a hospital organization without regard to the number of hospital facilities it operates that have failed the section 501(r)(3) requirements, a hospital organization operating multiple facilities may choose to pay the tax rather than conduct a CHNA and adopt an implementation strategy for every facility it operates.

The Treasury Department and the IRS note that section 501(r)(2)(B)(i) requires a hospital organization operating more than one hospital facility to meet the CHNA requirements ''separately with respect to each such facility'' and section 501(r)(2)(B)(ii) suggests that one hospital organization can fail to meet the CHNA requirements separately with respect to each hospital facility. Thus, a hospital organization with multiple hospital facilities can ''fail[] to meet the requirements of section 501(r)(3)'' within the meaning of section 4959 separately with respect to each hospital facility. Accordingly, these proposed regulations adopt the approach in Notice 2011–52 of applying the excise tax on a facility-by-facility basis.

One commenter requested clarification that the excise tax will be imposed on any hospital organization that fails to satisfy any requirement under section 501(r)(3), including the requirement to adopt an implementation strategy, and is not limited to a failure related to conducting the CHNA. These proposed regulations, in adopting the approach taken in Notice 2011–52, clarify that the excise tax is imposed on a failure to meet any of the requirements under section 501(r)(3), including the requirement to adopt an implementation strategy described in section 501(r)(3)(A)(ii).

Effective/Applicability Dates

The 2012 proposed regulations under section 501(r)(4) through (r)(6) were proposed to apply for taxable years beginning on or after the date those rules are published in the **Federal Register** as final or temporary regulations. By contrast, these proposed regulations provide that both these proposed regulations and the 2012 proposed regulations will generally be effective on the date these rules are published in the **Federal Register** as final or temporary regulations. Providing for an immediate effective date gives immediate effect to the transition relief described in § 1.501(r)–3(e) and will also allow the Treasury Department and the IRS to consider transition relief for the requirements under § 1.501(r)–4 through § 1.501(r)–6 of the 2012 proposed regulations based on the estimated amount of time to come into compliance with those rules rather than a particular hospital organization's taxable year. The proposed regulations under sections 6033(b)(10) and (b)(15)(A) are proposed to be effective for returns filed on or after the date these rules are published in the **Federal Register** as final or temporary regulations.

A hospital facility may rely on § 1.501(r)–3 of these proposed regulations for any CHNA conducted or implementation strategy adopted on or before the date that is six months after the date these proposed regulations are published as final or temporary regulations in the **Federal Register**. As provided in Notice 2011–52, hospital organizations may continue to rely on the interim rules described in Notice 2011–52 for any CHNA conducted or implementation strategy adopted on or before October 5, 2013, which is the date that is six months after these proposed regulations are published. After October 5, 2013, Notice 2011–52 is obsolete. The Treasury Department and the IRS invite comments on whether, and what type of, additional transitional relief may be necessary.

Hospital organizations should note that the statutory effective date of section 501(r)(3) is a hospital organization's first taxable year beginning after March 23, 2012. The effective date for the other requirements under section 501(r) is a hospital organization's first taxable year beginning after March 23, 2010.

Availability of IRS Documents

IRS notices, revenue rulings, and revenue procedures cited in this preamble are made available by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866, as supplemented by Executive Order 13563. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to this proposed regulation. It is hereby certified that the collection of information in these regulations will not have a significant economic impact on a substantial number of small entities. The collection of information is in § 1.501(r)–3 and § 1.6033–2(a)(2)(ii)(l) of the regulations. This certification is based on the following:

Consistent with the requirements imposed by statute, § 1.501(r)–3 of the regulations requires hospital facilities to conduct a CHNA and adopt an implementation strategy. However, these requirements need only be satisfied once over a period of three taxable years. Moreover, some hospital facilities already conduct similar community needs assessments under state law, and the Treasury Department and the IRS expect that these facilities will be able to draw upon pre-existing processes and resources to some extent.

Consistent with the requirements imposed by statute, § 1.6033–2(a)(2)(ii)(l) of the regulations requires affected organizations to report annually on a Form 990 actions taken during the year to address community health needs and to attach audited financial statements to the Form 990. To assist the IRS and the public, the regulations also require affected organizations to attach to the Form 990 a copy of the most recently adopted implementation strategy or provide the URL of a Web page where it is available to the public. For affected organizations, the burden of providing either a copy of the implementation strategy or the address of a Web site where it can be found will be minimal. Consequently, the regulations do not add to the impact on small entities imposed by the statutory scheme.

For these reasons, the collection of information in this regulation that is subject to the Regulatory Flexibility Act will not impose a significant economic burden upon the affected organizations. Accordingly, a Regulatory Flexibility Analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required. Pursuant to section 7805(f) of the Code, this regulation has been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small entities.

Comments and Requests for Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any comments that are submitted timely to the IRS as prescribed in this preamble

under **ADDRESSES**. The Treasury Department and the IRS request comments on all aspects of the proposed rules. All comments will be available at *www.regulations.gov* or upon request.

A public hearing will be scheduled if requested in writing by any person that timely submits written comments. If a public hearing is scheduled, notice of the date, time, and place for the public hearing will be published in the **Federal Register**.

Drafting Information

The principal authors of these proposed regulations are Preston J. Quesenberry and Amy F. Giuliano, Office of the Chief Counsel (Tax-Exempt and Government Entities). However, other personnel from the Treasury Department and the IRS participated in their development.

List of Subjects

26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 53

Excise taxes, Foundations, Investments, Lobbying, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR parts 1 and 53 are proposed to be amended as follows:

PART 1—INCOME TAXES

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

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

■ **Par. 2.** Section 1.501(r)–0 as proposed to be amended at 77 FR 38160 (June 26, 2012) is proposed to be further amended as follows:

■ 1. Adding a new entry to § 1.501(r)–1, paragraph (c).

■ 2. Adding new entries to § 1.501(r)–2 and § 1.501(r)–3.

■ 3. Revising the entry to § 1.501(r)–7.

The revision and additions to read as follows:

§ 1.501(r)–0 Outline of regulations.

* * * * *

§ 1.501(r)–1 Definitions.

* * * * *

(c) Additional definitions.

(1) Authorized body of a hospital facility.

(2) Operating a hospital facility.

(3) Partnership agreement.

(4) Widely available on a Web site.

§ 1.501(r)–2 Failures to satisfy section 501(r).

(a) Revocation of section 501(c)(3) status.

(b) Minor and inadvertent omissions and errors.

(c) Excusing certain failures if hospital facility corrects and discloses.

(d) Taxation of noncompliant hospital facilities.

(1) In general.

(2) Noncompliant facility income.

(3) No aggregation.

(4) Interaction with other Code provisions.

§ 1.501(r)-3 Community health needs assessments.

(a) In general.

(b) Conducting a CHNA.

(1) In general.

(2) Date a CHNA is conducted.

(3) Community served by the hospital facility.

(4) Assessing community health needs.

(5) Persons representing the broad interests of the community.

(6) Medically underserved populations.

(7) Documentation of a CHNA.

(8) Making the CHNA report widely available to the public.

(c) Implementation strategy.

(1) In general.

(2) Description of how the hospital facility plans to address a significant health need.

(3) Description of why a hospital facility is not addressing a significant health need.

(4) Joint implementation strategies.

(5) When the implementation strategy must be adopted.

(d) New hospital facilities.

(e) Transition rules.

(1) CHNA conducted in taxable year beginning before March 23, 2012.

(2) CHNA conducted in first taxable year beginning after March 23, 2012.

* * * * *

§ 1.501(r)–7 Effective/applicability dates.

(a) Effective/applicability date.

(b) Reliance and transition period.

■ **Par. 3.** Section 1.501(r)–1 as proposed to be amended at 77 FR 38160 (June 26, 2012) is proposed to be further amended by revising paragraphs (b)(15) and (b)(16) and adding new paragraph (c) to read as follows:

§ 1.501(r)–1 Definitions.

* * * * *

(b) * * *

(15) *Hospital facility* means a facility that is required by a state to be licensed, registered, or similarly recognized as a hospital. Multiple buildings operated under a single state license are considered to be a single hospital facility. For purposes of this paragraph (b)(15), the term ''state'' includes only the 50 states and the District of Columbia and not any U.S. territory or foreign country. References to a hospital facility taking actions include instances in which the hospital organization operating the hospital facility takes actions through or on behalf of the hospital facility.

(16) *Hospital organization* means an organization recognized (or seeking to be recognized) as described in section 501(c)(3) that operates one or more hospital facilities. If the section 501(c)(3) status of such an organization is revoked, the organization will, for purposes of section 4959, continue to be treated as a hospital organization during the taxable year in which such revocation becomes effective.

* * * * *

(c) *Additional definitions*—(1) *Authorized body of a hospital facility* means—

(i) The governing body (that is, the board of directors, board of trustees, or equivalent controlling body) of the hospital organization that operates the hospital facility, or a committee of, or other party authorized by, that governing body to the extent such committee or other party is permitted under state law to act on behalf of the governing body; or

(ii) If the hospital facility has its own governing body and is recognized as an entity under state law but is a disregarded entity for federal tax purposes, the governing body of that hospital facility, or a committee of, or other party authorized by, that governing body to the extent such committee or other party is permitted under state law to act on behalf of the governing body.

(2) *Operating a hospital facility* includes operating the facility through the organization's own employees or contracting out to another organization to operate the facility. For example, if an organization hires a management company to operate the facility, the hiring organization is considered to operate the facility. An organization also operates a hospital facility if it is the sole member or owner of a disregarded entity that operates the hospital facility. In addition, an organization operates a hospital facility if it owns a capital or profits interest in, or is a member of, a joint venture, limited liability company, or other entity treated as a partnership for federal income tax purposes that operates the hospital facility unless either—

(i) The organization does not have control over the operation of the hospital facility sufficient to ensure that the operation of the hospital facility furthers an exempt purpose described in section 501(c)(3) and thus treats the operation of the hospital facility, including the facility's provision of medical care, as an unrelated trade or business described in section 513(a) with respect to the hospital organization; or

(ii) At all times since March 23, 2010, the organization has been organized and operated primarily for educational or scientific purposes and has not engaged primarily in the operation of one or more hospital facilities and, pursuant to a partnership agreement entered into prior to March 23, 2010,—

(A) Does not own more than 35 percent of the capital or profits interest in the partnership (determined in accordance with section 707(b)(3));

(B) Does not own a general partner interest, managing-member interest, or similar interest in the partnership; and

(C) Does not have control over the operation of the hospital facility sufficient to ensure that the hospital facility complies with the requirements of section 501(r).

(3) *Partnership agreement,* for purposes of paragraph (c)(2)(ii) of this section, includes all written agreements among the partners, or between one or more partners and the partnership, concerning affairs of the partnership and responsibilities of the partners, whether or not embodied in a document referred to by the partners as the partnership agreement, entered into before March 23, 2010. A partnership agreement also includes any modifications to the agreement agreed to by all partners, or adopted in any other manner provided by the partnership agreement, but no such modifications adopted on or after March 23, 2010, that affect whether or not the agreement is described in paragraph (c)(2)(ii) of this section. In addition, a partnership agreement includes provisions of Federal, state, or local law, as in effect before March 23, 2010, that govern the affairs of the partnership or are considered under such law to be part of the partnership agreement.

(4) *Widely available on a Web site* means—

(i) The hospital facility conspicuously posts a complete and current version of the document on—

(A) The hospital facility's Web site;

(B) If the hospital facility does not have its own Web site separate from the hospital organization that operates it, the hospital organization's Web site; or

(C) A Web site established and maintained by another entity, but only if the Web site of the hospital facility or hospital organization (if the facility or organization has a Web site) provides a conspicuously-displayed link to the Web page on which the document is posted, along with clear instructions for accessing the document on that Web site;

(ii) Individuals with access to the Internet can access, download, view, and print a hard copy of the document without requiring special computer hardware or software (other than software that is readily available to members of the public without payment of any fee); without payment of a fee to the hospital facility, hospital organization, or other entity maintaining the Web site; and without creating an account or being otherwise required to provide personally identifiable information; and

(iii) The hospital facility provides individuals who ask how to access a copy of the document online with the direct Web site address, or URL, of the Web page on which the document is posted.

■ **Par. 4.** Sections 1.501(r)–2 and 1.501(r)–3 are added to read as follows:

§ 1.501(r)–2 Failures to satisfy section 501(r).

(a) *Revocation of section 501(c)(3) status.* Except as otherwise provided in paragraphs (b) and (c) of this section, a hospital organization failing to meet one or more of the requirements of section 501(r) separately with respect to one or more hospital facilities it operates may have its section 501(c)(3) status revoked as of the first day of the taxable year in which the failure occurs. In determining whether to continue to recognize the section 501(c)(3) status of a hospital organization that fails to meet one or more of the requirements of section 501(r) with respect to one or more hospital facilities, the Commissioner will consider all relevant facts and circumstances including, but not limited to, the following—

(1) Whether the organization has previously failed to meet the requirements of section 501(r), and, if so, whether the same type of failure previously occurred;

(2) The size, scope, nature, and significance of the organization's failure(s);

(3) In the case of an organization that operates more than one hospital facility, the number, size, and significance of the facilities that have failed to meet the section 501(r) requirements relative to those that have complied with these requirements;

(4) The reason for the failure(s);

(5) Whether the organization had, prior to the failure(s), established practices and procedures (formal or informal) reasonably designed to promote and facilitate overall compliance with the section 501(r) requirements;

(6) Whether the practices and procedures had been routinely followed and the failure(s) occurred through an oversight or mistake in applying them;

(7) Whether the organization has implemented safeguards that are reasonably calculated to prevent similar failures from occurring in the future;

(8) Whether the organization corrected the failure(s) as promptly after discovery as is reasonable given the nature of the failure(s); and

(9) Whether the organization took the measures described in paragraphs (a)(7) and (a)(8) of this section before the Commissioner discovered the failure(s).

(b) *Minor and inadvertent omissions and errors.* A hospital facility's omission of required information from a policy or report described in § 1.501(r)–3 or § 1.501(r)–4, or error with respect to the implementation or operational requirements described in § 1.501(r)–3 through § 1.501(r)–6, will not be considered a failure to meet a requirement of section 501(r) if—

(1) Such omission or error was minor, inadvertent, and due to reasonable cause; and

(2) The hospital facility corrects such omission or error as promptly after discovery as is reasonable given the nature of the omission or error.

(c) *Excusing certain failures if hospital facility corrects and discloses.* Pursuant to guidance set forth by revenue procedure, notice, or other guidance published in the Internal Revenue Bulletin, a hospital facility's failure to meet one or more of the requirements described in § 1.501(r)–3 through § 1.501(r)–6 that is neither willful nor egregious shall be excused for purposes of this section if the hospital facility corrects and makes disclosure in accordance with the rules set forth in the guidance. If a hospital facility's failure was willful or egregious, the failure will not be excused, even if the hospital facility corrects and makes disclosure in accordance with the guidance, and no presumption will be created by a hospital facility's correction and disclosure that the failure was neither willful nor egregious. For purposes of this paragraph (c), willful is to be interpreted consistent with the meaning of that term in the context of civil penalties, which would include a failure due to gross negligence, reckless

disregard, or willful neglect. Furthermore, notwithstanding a hospital facility's compliance with such future guidance, a hospital facility may, in the discretion of the IRS, be subject to an excise tax under section 4959 for failures to meet the requirements of section 501(r)(3).

(d) *Taxation of noncompliant hospital facilities*—(1) *In general.* Except as otherwise provided in paragraphs (b) and (c) of this section, if a hospital organization that operates more than one hospital facility fails to meet one or more of the requirements of section 501(r) separately with respect to a hospital facility during a taxable year, the income derived from the noncompliant hospital facility (''noncompliant facility income'') during that taxable year will be subject to tax computed as provided in section 11 (or as provided in section 1(e) if the hospital organization is a trust described in section 511(b)(2)), but substituting ''noncompliant facility income'' for ''taxable income,'' if—

(i) The hospital organization continues to be recognized as described in section 501(c)(3) during the taxable year, but

(ii) The hospital organization would not continue to be recognized as described in section 501(c)(3) during the taxable year based on the facts and circumstances described in paragraph (a) of this section (but disregarding paragraph (a)(3)) if the noncompliant hospital facility were the only hospital facility operated by the organization.

(2) *Noncompliant facility income*—(i) *In general.* For purposes of this paragraph (d), the noncompliant facility income derived from a hospital facility during a taxable year will be the gross income derived from that hospital facility during the taxable year, less the deductions allowed by chapter 1 of the Internal Revenue Code (Code) that are directly connected to the operation of that hospital facility during the taxable year, excluding any gross income and deductions taken into account in computing any unrelated business taxable income described in section 512 that is derived from the facility during the taxable year.

(ii) *Directly connected deductions.* For purposes of this paragraph (d), to be directly connected with the operation of a hospital facility that has failed to meet the requirements of section 501(r), an item of deduction must have proximate and primary relationship to the operation of the hospital facility. Expenses, depreciation, and similar items attributable solely to the operation of a hospital facility are proximately and primarily related to such operation, and therefore qualify for deduction to the extent that they meet the requirements of section 162, section 167, or other relevant provisions of the Code. Where expenses, depreciation, and similar items are attributable to a noncompliant hospital facility and other hospital facilities operated by the hospital organization (and/or to other activities of the hospital organization unrelated to the operation of hospital facilities), such items shall be allocated between the hospital facilities (and/or other activities) on a reasonable basis. The portion of any such item so allocated to a noncompliant hospital facility is proximately and primarily related to the operation of that facility and shall be allowable as a deduction in computing the facility's noncompliant facility income in the manner and to the extent it would meet the requirements of section 162, section 167, or other relevant provisions of the Code.

(3) *No aggregation.* In computing the noncompliant facility income of a hospital facility, the gross income from (and the deductions allowed with respect to) the hospital facility may not be aggregated with the gross income from (and the deductions allowed with respect to) the hospital organization's other noncompliant hospital facilities subject to tax under this paragraph (d) or its unrelated trade or business activities described in section 513.

(4) *Interaction with other Code provisions*—(i) *Hospital organization operating a noncompliant hospital facility continues to be treated as tax-exempt.* A hospital organization operating a noncompliant hospital facility subject to tax under this paragraph (d) shall continue to be treated as an organization that is exempt from tax under section 501(a) because it is described in section 501(c)(3) for all purposes of the Code. Thus, for example, the application of this paragraph (d) shall not, by itself, affect the tax-exempt status of bonds issued to finance the noncompliant hospital facility.

(ii) *Noncompliant hospital facility operated by a tax-exempt hospital organization is subject to tax.* A noncompliant hospital facility described in paragraph (d)(1) of this section is subject to tax under this paragraph (d), notwithstanding the fact that the hospital organization operating the hospital facility is otherwise exempt from tax under section 501(a) and subject to tax under section 511(a) and that § 1.11–1(a) of this chapter states such organizations are not liable to the tax imposed under section 11.

(iii) *Noncompliant hospital facility not a business entity.* A noncompliant hospital facility subject to tax under this paragraph (d) is not considered a business entity for purposes of § 301.7701–2(b)(7) of this chapter.

§ 1.501(r)–3 Community health needs assessments.

(a) *In general.* With respect to any taxable year, a hospital organization meets the requirements of section 501(r)(3) with respect to a hospital facility it operates only if—

(1) The hospital facility has conducted a community health needs assessment (CHNA) that meets the requirements of paragraph (b) of this section in such taxable year or in either of the two taxable years immediately preceding such taxable year; and

(2) An authorized body of the hospital facility (as defined in § 1.501(r)–1(c)(1)) has adopted an implementation strategy to meet the community health needs identified through the CHNA, as described in paragraph (c) of this section, by the end of the taxable year in which the hospital facility conducts the CHNA.

(b) *Conducting a CHNA*—(1) *In general.* To conduct a CHNA for purposes of paragraph (a) of this section, a hospital facility must complete all of the following steps—

(i) Define the community it serves;

(ii) Assess the health needs of that community;

(iii) In assessing the health needs of the community, take into account input from persons who represent the broad interests of that community, including those with special knowledge of or expertise in public health;

(iv) Document the CHNA in a written report (''CHNA report'') that is adopted for the hospital facility by an authorized body of the hospital facility; and

(v) Make the CHNA report widely available to the public.

(2) *Date a CHNA is conducted.* For purposes of this section, a hospital facility will be considered to have conducted a CHNA on the date it has completed all of the steps described in paragraph (b)(1) of this section. Solely for purposes of determining the date on which a CHNA has been conducted, a hospital facility will be considered to have made the CHNA report widely available to the public on the date it first makes the CHNA report widely available to the public as described in paragraph (b)(8)(i) of this section.

(3) *Community served by the hospital facility.* In defining the community it serves for purposes of paragraph (b)(1)(i) of this section, a hospital facility may take into account all of the relevant facts and circumstances, including the geographic area served by the hospital

facility, target populations served (for example, children, women, or the aged), and principal functions (for example, focus on a particular specialty area or targeted disease). A hospital facility may define its community to include populations in addition to its patient populations and geographic areas outside of those in which its patient populations reside. However, a hospital facility may not define its community to exclude medically underserved, low-income, or minority populations who are part of its patient populations, live in geographic areas in which its patient populations reside (unless they are not part of the hospital facility's target populations or affected by its principal functions), or otherwise should be included based on the method the hospital facility uses to define its community. In addition, if a hospital facility's method of defining its community takes into account patient populations, the hospital facility must treat as patients all individuals who receive care from the hospital facility, without regard to whether (or how much) they or their insurers pay for the care received or whether they are eligible for assistance under the hospital facility's financial assistance policy.

(4) *Assessing community health needs.* To assess the health needs of the community it serves for purposes of paragraph (b)(1)(ii) of this section, a hospital facility must identify significant health needs of the community, prioritize those health needs, and identify potential measures and resources (such as programs, organizations, and facilities in the community) available to address the health needs. For these purposes, the health needs of a community include requisites for the improvement or maintenance of health status in both the community at large and in particular parts of the community (such as particular neighborhoods or populations experiencing health disparities). A hospital facility may determine whether a health need is significant based on all of the facts and circumstances present in the community it serves. In addition, a hospital facility may use any criteria to prioritize the significant health needs it identifies, including, but not limited to, the burden, scope, severity, or urgency of the health need; the estimated feasibility and effectiveness of possible interventions; the health disparities associated with the need; or the importance the community places on addressing the need.

(5) *Persons representing the broad interests of the community.* To take into account input from persons who represent the broad interests of the community it serves (including those with special knowledge of or expertise in public health) for purposes of paragraph (b)(1)(iii) of this section, a hospital facility must take into account input from the sources listed in paragraphs (b)(5)(i), (b)(5)(ii), and (b)(5)(iii) of this section in assessing the health needs of its community. Input from these persons includes, but is not limited to, input on any financial and other barriers to access to care in the community. In addition, a hospital facility may take into account input from a broad range of persons located in or serving its community, including, but not limited to, health care consumers and consumer advocates, nonprofit and community-based organizations, academic experts, local government officials, local school districts, health care providers and community health centers, health insurance and managed care organizations, private businesses, and labor and workforce representatives. A hospital facility must take into account input from the following sources in assessing the health needs of its community—

(i) At least one state, local, tribal, or regional governmental public health department (or equivalent department or agency) with knowledge, information, or expertise relevant to the health needs of that community;

(ii) Members of medically underserved, low-income, and minority populations in the community served by the hospital facility, or individuals or organizations serving or representing the interests of such populations; and

(iii) Written comments received on the hospital facility's most recently conducted CHNA and most recently adopted implementation strategy.

(6) *Medically underserved populations.* For purposes of this paragraph (b), medically underserved populations include populations experiencing health disparities or at risk of not receiving adequate medical care as a result of being uninsured or underinsured or due to geographic, language, financial, or other barriers.

(7) *Documentation of a CHNA*—(i) *In general.* For purposes of paragraph (b)(1)(iv) of this section, the CHNA report adopted for the hospital facility by an authorized body of the hospital facility must include—

(A) A definition of the community served by the hospital facility and a description of how the community was determined;

(B) A description of the process and methods used to conduct the CHNA;

(C) A description of how the hospital facility took into account input from persons who represent the broad interests of the community it serves;

(D) A prioritized description of the significant health needs of the community identified through the CHNA, along with a description of the process and criteria used in identifying certain health needs as significant and prioritizing such significant health needs; and

(E) A description of the potential measures and resources identified through the CHNA to address the significant health needs.

(ii) *Process and methods used to conduct the CHNA.* A hospital facility's CHNA report will be considered to describe the process and methods used to conduct the CHNA for purposes of paragraph (b)(7)(i)(B) of this section if the CHNA report describes the data and other information used in the assessment, as well as the methods of collecting and analyzing this data and information, and identifies any parties with whom the hospital facility collaborated, or with whom it contracted for assistance, in conducting the CHNA.

(iii) *Input from persons who represent the broad interests of the community served by the hospital facility.* A hospital facility's CHNA report will be considered to describe how the hospital facility took into account input from persons who represent the broad interests of the community it serves for purposes of paragraph (b)(7)(i)(C) of this section if the CHNA report summarizes, in general terms, the input provided by such persons and how and over what time period such input was provided (for example, whether through meetings, focus groups, interviews, surveys, or written comments and between what dates); provides the names of organizations providing input and summarizes the nature and extent of the organization's input; and describes the medically underserved, low-income, or minority populations being represented by organizations or individuals that provided input. A CHNA report does not need to name or otherwise individually identify any individuals participating in community forums, focus groups, survey samples, or similar groups.

(iv) *Separate CHNA reports.* While a hospital facility may conduct its CHNA in collaboration with other organizations and facilities (including, but not limited to, related and unrelated hospital organizations and facilities, for-profit and government hospitals, governmental departments, and nonprofit organizations), every hospital facility must document the information described in this paragraph (b)(7) in a

separate CHNA report to satisfy paragraph (b)(1)(iv) of this section unless it is eligible to adopt a joint CHNA report as described in paragraph (b)(7)(v) of this section. However, if a hospital facility is collaborating with other facilities and organizations in conducting its CHNA or if another organization has conducted a CHNA for all or part of the hospital facility's community, portions of the hospital facility's CHNA report may be substantively identical to portions of a CHNA report of a collaborating hospital facility or the other organization conducting a CHNA, if appropriate under the facts and circumstances. For example, if a hospital facility conducts a survey of the health needs of residents of homeless shelters located in the community in collaboration with other hospital facilities, the description of that survey in the hospital facility's CHNA report may be identical to the description contained in the CHNA reports for the other collaborating hospital facilities. Similarly, if the state or local public health department with jurisdiction over the community served by the hospital facility conducts an inventory of community health improvement resources available in that community, the hospital facility may include that inventory in its CHNA report.

(v) *Joint CHNA reports*—(A) *In general.* A hospital facility that collaborates with other hospital facilities in conducting its CHNA will satisfy paragraph (b)(1)(iv) of this section if an authorized body of the hospital facility adopts for the hospital facility a joint CHNA report produced for all of the collaborating hospital facilities, as long as all of the collaborating hospital facilities define their community to be the same and conduct a joint CHNA process, and the joint CHNA report is clearly identified as applying to the hospital facility.

(B) *Example.* The following example illustrates this paragraph (b)(7)(v):

Example. P is one of ten hospital facilities located in and serving the populations of a particular Metropolitan Statistical Area (MSA). P and the other nine facilities in the MSA, some of which are unrelated to P, decide to collaborate in conducting a CHNA for the MSA and to each define their community as constituting the entire MSA. The ten hospital facilities work together with the state and local health departments of jurisdictions in the MSA to assess the health needs of the MSA and collaborate in conducting surveys and holding public forums to receive input from the MSA's residents, including its medically underserved, low-income, and minority populations. The hospital facilities then work together to prepare a joint CHNA report documenting this joint CHNA process that contains all of the elements described in paragraph (b)(7)(i) of this section. The joint CHNA report identifies all of the collaborating hospital facilities, including P, by name, both within the report itself and on the cover page. The board of directors of the hospital organization operating P adopts the joint CHNA report for P. P has complied with the requirements of this paragraph (b)(7)(v) and, accordingly, has satisfied paragraph (b)(1)(iv) of this section.

(8) *Making the CHNA report widely available to the public*—(i) *In general.* For purposes of paragraph (b)(1)(v) of this section, a hospital facility's CHNA report is made widely available to the public only if the hospital facility—

(A) Makes the CHNA report widely available on a Web site, as defined in § 1.501(r)-1(c)(4), at least until the date the hospital facility has made widely available on a Web site its two subsequent CHNA reports; and

(B) Makes a paper copy of the CHNA report available for public inspection without charge at the hospital facility at least until the date the hospital facility has made available for public inspection without charge a paper copy of its two subsequent CHNA reports.

(ii) *Making draft CHNA reports widely available.* Notwithstanding paragraph (b)(8)(i) of this section, if a hospital facility makes widely available on a Web site (and/or for public inspection) a version of the CHNA report that is expressly marked as a draft on which the public may comment, the hospital facility will not be considered to have made the CHNA report widely available to the public for purposes of determining the date on which the hospital facility has conducted a CHNA under paragraph (a) of this section.

(c) *Implementation strategy*—(1) *In general.* For purposes of paragraph (a)(2) of this section, a hospital facility's implementation strategy to meet the community health needs identified through the hospital facility's CHNA is a written plan that, with respect to each significant health need identified through the CHNA, either—

(i) Describes how the hospital facility plans to address the health need; or

(ii) Identifies the health need as one the hospital facility does not intend to address and explains why the hospital facility does not intend to address the health need.

(2) *Description of how the hospital facility plans to address a significant health need.* In describing how a hospital facility plans to address a significant health need identified through a CHNA for purposes of paragraph (c)(1)(i) of this section, the implementation strategy must describe the actions the hospital facility intends to take to address the health need, the anticipated impact of these actions, and a plan to evaluate such impact. The implementation strategy must also identify the programs and resources the hospital facility plans to commit to address the health need. Finally, the implementation strategy must describe any planned collaboration between the hospital facility and other facilities or organizations in addressing the health need.

(3) *Description of why a hospital facility is not addressing a significant health need.* In explaining why it does not intend to address a significant health need for purposes of paragraph (c)(1)(ii) of this section, a hospital facility may provide a brief explanation of its reason for not addressing the health need, including, but not limited to, resource constraints, other facilities or organizations in the community addressing the need, relative lack of expertise or competencies to effectively address the need, a relatively low priority assigned to the need, and/or a lack of identified effective interventions to address the need.

(4) *Joint implementation strategies.* A hospital facility may develop an implementation strategy in collaboration with other facilities and organizations, including, but not limited to, related and unrelated hospital organizations and facilities, for-profit and government hospitals, governmental departments, and nonprofit organizations. In general, a hospital facility that collaborates with other facilities and organizations in developing its implementation strategy must still document its implementation strategy in a separate written plan that is tailored to the particular hospital facility, taking into account its specific programs and resources. However, a hospital facility that adopts a joint CHNA report described in paragraph (b)(7)(v) of this section may also adopt a joint implementation strategy that, with respect to each significant health need identified through the joint CHNA, either describes how the collaborating hospital facilities plan to address the health need or identifies the health need as one the hospital facilities do not intend to address and explains why the hospital facilities do not intend to address the health need, as long as the joint implementation strategy—

(i) Is clearly identified as applying to the hospital facility;

(ii) Clearly identifies the hospital facility's particular role and responsibilities in taking the actions described in the implementation strategy and the programs and resources

the hospital facility plans to commit to such actions; and

(iii) Includes a summary or other tool that helps the reader easily locate those portions of the joint implementation strategy that relate to the hospital facility.

(5) *When the implementation strategy must be adopted*—(i) *In general.* For purposes of paragraph (a)(2) of this section, in order to have adopted an implementation strategy to meet the health needs identified through a hospital facility's CHNA by the end of the same taxable year in which the hospital facility conducts that CHNA, an authorized body of the hospital facility must adopt the implementation strategy during the taxable year in which the hospital facility completes the final step for the CHNA described in paragraph (b)(1) of this section, regardless of whether the hospital facility began working on the CHNA in a prior taxable year.

(ii) *Example.* The following example illustrates this paragraph (c)(5):

Example. M is a hospital facility that last conducted a CHNA and adopted an implementation strategy in Year 1. In Year 3, M defines the community it serves, assesses the health needs of that community, and takes into account input from persons who represent the broad interests of that community. In Year 4, M documents its CHNA in a CHNA report that is adopted by an authorized body of M, makes the CHNA report widely available on a Web site, and makes paper copies available for public inspection. To meet the requirements of paragraph (a)(2) of this section, an authorized body of M must adopt an implementation strategy to meet the health needs identified through that CHNA by the last day of Year 4.

(d) *New hospital facilities.* A hospital facility that is newly acquired or placed into service, or that becomes newly subject to the requirements of section 501(r) because the hospital organization that operates it is newly recognized as described in section 501(c)(3), must meet the requirements of section 501(r)(3) by the last day of the second taxable year beginning after the date, respectively, the hospital facility is acquired; licensed, registered, or similarly recognized by its state as a hospital; or newly subject to the requirements of section 501(r) as a result of the hospital organization operating it being recognized as described in section 501(c)(3).

(e) *Transition rules*—(1) *CHNA conducted in taxable year beginning before March 23, 2012.* A hospital facility that conducted a CHNA described in section 501(r)(3) in either its first taxable year beginning after March 23, 2010, or its first taxable year beginning after March 23, 2011, does not need to meet the requirements of section 501(r)(3) again until the third taxable year following the taxable year in which the hospital facility conducted that CHNA, provided that the hospital facility has adopted an implementation strategy to meet the community health needs identified through that CHNA on or before the 15th day of the fifth calendar month following the close of its first taxable year beginning after March 23, 2012.

(2) *CHNA conducted in first taxable year beginning after March 23, 2012.* A hospital facility that conducts a CHNA described in section 501(r)(3) in its first taxable year beginning after March 23, 2012, will be deemed to satisfy paragraph (a)(2) of this section during that taxable year if an authorized body of the hospital facility adopts an implementation strategy to meet the community health needs identified through that CHNA on or before the 15th day of the fifth calendar month following the close of its first taxable year beginning after March 23, 2012.

■ **Par. 5.** Section 1.501(r)–7 as proposed to be amended at 77 FR 38169 (June 26, 2012) is proposed to be further amended by revising the section to read as follows:

§ 1.501(r)–7 Effective/applicability dates.

(a) *Effective/applicability date.* The rules of § 1.501(r)–1 through § 1.501(r)–6 are effective on the date of publication of the Treasury decision adopting these rules as final or temporary regulations.

(b) *Reliance and transition period.* A hospital facility may rely on § 1.501(r)–3 of the proposed regulations published in the **Federal Register** on April 5, 2013, for any CHNA conducted or implementation strategy adopted on or before the date that is six months after these regulations are published as final or temporary regulations in the **Federal Register**.

■ **Par. 6.** Section 1.6012–2 is amended by redesignating paragraphs (i) through (k) as paragraphs (j) through (l) and adding new paragraph (i) to read as follows:

§ 1.6012–2 Corporations required to make returns of income.

* * * * *

(i) *Hospital organizations with noncompliant hospital facilities.* Every hospital organization (as defined in § 1.501(r)–1(b)(16)) that is subject to the tax imposed by § 1.501(r)–2(d) shall make a return on Form 990–T. The filing of a return to pay the tax described in § 1.501(r)–2(d) does not relieve the organization of the duty of filing other required returns.

* * * * *

■ **Par. 7.** Section 1.6012–3 is amended by adding new paragraph (a)(10) to read as follows:

§ 1.6012–3 Returns by fiduciaries.

(a) * * *

(10) *Hospital organizations organized as trust with noncompliant hospital facilities.* Every fiduciary for a hospital organization (as defined in § 1.501(r)–1(b)(16)) organized as a trust described in section 511(b)(2) that is subject to the tax imposed by § 1.501(r)–2(d) shall make a return on Form 990–T. The filing of a return to pay the tax described in § 1.501(r)–2(d) does not relieve the organization of the duty of filing other required returns.

* * * * *

■ **Par. 8.** Section 1.6033–2 is amended by adding paragraphs (a)(2)(ii)(*l*) and (k)(4) to read as follows:

§ 1.6033–2 Returns by exempt organizations (taxable years beginning after December 31, 1969) and returns by certain nonexempt organizations (taxable years beginning after December 31, 1980).

(a) * * *

(2) * * *

(ii) * * *

(*l*) In the case of a hospital organization (as defined in § 1.501(r)–1(b)(16)) described in section 501(c)(3) during the taxable year—

(*1*) A copy of its audited financial statements for the taxable year (or, in the case of an organization the financial statements of which are included in consolidated financial statements with other organizations, such consolidated financial statements);

(*2*) Either a copy of the most recently adopted implementation strategy, within the meaning of § 1.501(r)–3(c), for each hospital facility it operates or the URL of each Web page on which it has made each such implementation strategy widely available on a Web site within the meaning of § 1.501(r)–1(c)(4) along with or as part of the community health needs assessment (CHNA) to which the implementation strategy relates;

(*3*) For each hospital facility it operates, a description of the actions taken during the taxable year to address the significant health needs identified through its most recently conducted CHNA, within the meaning of § 1.501(r)–3(b), or, if no actions were taken with respect to one or more of these health needs, the reason(s) why no actions were taken; and

(*4*) The amount of the excise tax imposed on the organization under section 4959 during the taxable year.

* * * * *

(k) * * *

(4) The applicability of paragraph (a)(2)(ii)(*l*) of this section shall be limited to returns filed on or after the date the regulations adding (a)(2)(ii)(*l*) are published as final or temporary regulations in the **Federal Register**.

PART 53—FOUNDATION AND SIMILAR EXCISE TAXES

■ **Par. 9.** The authority citation for part 53 continues to read in part as follows:

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

■ **Par. 10.** Section 53.4959–1 is added to read as follows:

§ 53.4959–1 Taxes on failures by hospital organizations to meet section 501(r)(3).

(a) *Excise tax for failure to meet the section 501(r)(3) requirements*—(1) *In general.* If a hospital organization (as defined in § 1.501(r)–1(b)(16)) fails to meet the requirements of section 501(r)(3) separately with respect to a hospital facility it operates in any taxable year, there is imposed on the hospital organization a tax equal to $50,000. If a hospital organization operates multiple hospital facilities and fails to meet the requirements of section 501(r)(3) with respect to more than one facility it operates, the $50,000 tax is imposed on the hospital organization separately for each hospital facility's failure. The tax may be imposed for each taxable year that a hospital facility fails to meet the requirements of section 501(r)(3). The tax imposed by this section may be imposed in addition to any tax imposed by § 1.501(r)–2(d) or as a result of revocation of a hospital organization's section 501(c)(3) status.

(2) *Examples.* The following examples illustrate this paragraph (a):

Example 1. (i) U is a hospital organization that operates only one hospital facility, V. In Year 1, V conducts a community health needs assessment (CHNA) and adopts an implementation strategy to meet the health needs identified through the CHNA. In Years 2 and 3, V does not conduct a CHNA. V fails to conduct a CHNA by the last day of Year 4. Accordingly, U has failed to meet the requirements of section 501(r)(3) with respect to V in Year 4 because V has failed to conduct a CHNA in Years 2, 3, and 4. U is subject to a tax equal to $50,000 for Year 4.

(ii) V also fails to conduct a CHNA by the last day of Year 5. Accordingly, U has failed to meet the requirements of section 501(r)(3) with respect to V in Year 5 because V has failed to conduct a CHNA in Years 3, 4, and 5. U is subject to a tax equal to $50,000 for Year 5.

Example 2. P is a hospital organization that operates only one hospital facility, Q. In Year 1, Q conducts a CHNA and adopts an implementation strategy to meet the health needs identified through the CHNA. In Years 2 and 3, Q does not conduct a CHNA. In Year 4, Q conducts a CHNA but does not adopt an implementation strategy to meet the health needs identified through that CHNA by the last day of Year 4. Accordingly, P has failed to meet the requirements of section 501(r)(3) with respect to Q in Year 4 because Q has failed to adopt an implementation strategy by the end of the taxable year in which Q conducted its CHNA. P is subject to a tax equal to $50,000 for Year 4.

Example 3. R is a hospital organization that operates two hospital facilities, S and T. In Year 1, S and T each conduct a CHNA and adopt an implementation strategy to meet the health needs identified through the CHNA. In Years 2 and 3, S and T do not conduct a CHNA. S and T each fail to conduct a CHNA by the last day of Year 4. Accordingly, R has failed to meet the requirements of section 501(r)(3) with respect to both S and T in Year 4. R is subject to a tax equal to $100,000 ($50,000 for S's failure plus $50,000 for T's failure) for Year 4.

(b) *Effective/applicability dates.* These rules are effective on the date of publication of the Treasury decision adopting these rules as final or temporary regulations.

Steven T. Miller,

Deputy Commissioner for Services and Enforcement.

[FR Doc. 2013–07959 Filed 4–3–13; 4:15 pm]

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DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Part 9

[Docket No. TTB–2013–0003; Notice No. 134]

RIN 1513–AB99

Proposed Establishment of the Big Valley District–Lake County and Kelsey Bench–Lake County Viticultural Areas, and Modification of the Red Hills Lake County Viticultural Area

AGENCY: Alcohol and Tobacco Tax and Trade Bureau, Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Alcohol and Tobacco Tax and Trade Bureau (TTB) proposes to establish the 11,000-acre Big Valley District–Lake County viticultural area and the 9,100-acre Kelsey Bench–Lake County viticultural area, both in Lake County, California. Additionally, TTB proposes to modify the boundary of the established 31,250-acre Red Hills Lake County viticultural area in order to align its border with that of the proposed Kelsey Bench–Lake County viticultural area. The proposed modification would increase the size of the Red Hills Lake County viticultural area by approximately 7 acres. The proposed viticultural areas and the established viticultural area that are the subject of this proposed rule lie entirely within the existing Clear Lake viticultural area, which, in turn, is within the larger, multicounty North Coast viticultural area. TTB designates viticultural areas to allow vintners to better describe the origin of their wines and to allow consumers to better identify wines they may purchase. TTB invites comments on these proposed additions and modification to its regulations.

DATES: Comments must be received by June 4, 2013.

ADDRESSES: Please send your comments on this notice to one of the following addresses:

- *http://www.regulations.gov* (via the online comment form for this notice as posted within Docket No. TTB–2013–0003 at ''Regulations.gov,'' the Federal e-rulemaking portal);
- *U.S. mail:* Director, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Box 12, Washington, DC 20005; or
- *Hand delivery/courier in lieu of mail:* Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Suite 200–E, Washington, DC 20005.

See the Public Participation section of this notice for specific instructions and requirements for submitting comments, and for information on how to request a public hearing.

You may view copies of this notice, selected supporting materials, and any comments TTB receives about this proposal at *http://www.regulations.gov* within Docket No. TTB–2013–0003. A link to that docket is posted on the TTB Web site at *http://www.ttb.gov/wine/wine-rulemaking.shtml* under Notice No. 134. You also may view copies of this notice, all related petitions, maps or other supporting materials, and any comments TTB receives about this proposal by appointment at the TTB Information Resource Center, 1310 G Street NW., Washington, DC 20005. Please call 202–453–2270 to make an appointment.

FOR FURTHER INFORMATION CONTACT: Karen A. Thornton, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Box 12, Washington, DC 20005; phone 202–453–1039, ext. 175.

SUPPLEMENTARY INFORMATION:

Background on Viticultural Areas

TTB Authority

Section 105(e) of the Federal Alcohol Administration Act (FAA Act), 27 U.S.C. 205(e), authorizes the Secretary of the Treasury to prescribe regulations for the labeling of wine, distilled spirits, and malt beverages. The FAA Act provides that these regulations should, among other things, prohibit consumer deception and the use of misleading statements on labels, and ensure that labels provide the consumer with adequate information as to the identity and quality of the product. The Alcohol and Tobacco Tax and Trade Bureau (TTB) administers the FAA Act pursuant to section 1111(d) of the Homeland Security Act of 2002, codified at 6 U.S.C. 531(d). The Secretary has delegated various authorities through Treasury Department Order 120–01 (Revised), dated January 21, 2003, to the TTB Administrator to perform the functions and duties in the administration and enforcement of this law.

Part 4 of the TTB regulations (27 CFR part 4) allows the establishment of definitive viticultural areas and the use of their names as appellations of origin on wine labels and in wine advertisements. Part 9 of the TTB regulations (27 CFR part 9) contains the list of approved American viticultural areas.

Definition

Section 4.25(e)(1)(i) of the TTB regulations (27 CFR 4.25(e)(1)(i)) defines a viticultural area for American wine as a delimited grape-growing region having distinguishing features as described in part 9 of the regulations and a name and a delineated boundary as established in part 9 of the regulations. These designations allow vintners and consumers to attribute a given quality, reputation, or other characteristic of a wine made from grapes grown in an area to its geographic origin. The establishment of viticultural areas allows vintners to describe more accurately the origin of their wines to consumers and helps consumers to identify wines they may purchase. Establishment of a viticultural area is neither an approval nor an endorsement by TTB of the wine produced in that area.

Requirements

Section 4.25(e)(2) of the TTB regulations outlines the procedure for proposing an American viticultural area and provides that any interested party may petition TTB to establish a grape-growing region as a viticultural area.

Section 9.12 of the TTB regulations (27 CFR 9.12) prescribes standards for petitions for the establishment or modification of American viticultural areas. Petitions to establish a viticultural area must include the following:

- Evidence that the area within the proposed viticultural area boundary is nationally or locally known by the viticultural area name specified in the petition;
- An explanation of the basis for defining the boundary of the proposed viticultural area;
- A narrative description of the features of the proposed viticultural area that affect viticulture, such as climate, geology, soils, physical features, and elevation, that make the proposed viticultural area distinctive and distinguish it from adjacent areas outside the proposed viticultural area boundary;
- A copy of the appropriate United States Geological Survey (USGS) map(s) showing the location of the proposed viticultural area, with the boundary of the proposed viticultural area clearly drawn thereon; and
- A detailed narrative description of the proposed viticultural area boundary based on USGS map markings.

Big Valley District–Lake County and Kelsey Bench–Lake County Petitions

TTB received two petitions from Terry Dereniuk on behalf of the Big Valley District and Kelsey Bench Growers Committee proposing to establish the ''Big Valley District–Lake County'' and the ''Kelsey Bench–Lake County'' American viticultural areas within Lake County, California. The proposed Big Valley District–Lake County viticultural area has 6 bonded wineries and 43 vineyards containing approximately 1,800 acres of wine grapes. The proposed Kelsey Bench–Lake County viticultural area has 1 bonded winery and 27 vineyards planted with approximately 900 acres of wine grapes. Because the two petitions were submitted simultaneously and the two proposed viticultural areas share a common boundary, TTB is combining both proposals into a single rulemaking document. Unless otherwise noted, all information and data pertaining to the two proposed viticultural areas contained in this document are from the petitions for the two proposed viticultural areas and their supporting exhibits.

The proposed Big Valley District–Lake County and Kelsey Bench–Lake County viticultural areas are located in central Lake County, California. The proposed Big Valley District–Lake County viticultural area is located on the southern shore of Clear Lake, and the adjacent Kelsey Bench–Lake County viticultural area is located just to the south. The two proposed viticultural areas are surrounded by Mount Konocti and the Red Hills to the east and by the Mayacmas Mountains to the west and south. The two proposed viticultural areas lie entirely within the existing Clear Lake viticultural area (27 CFR 9.99) which, in turn, lies within the multicounty North Coast viticultural area (27 CFR 9.30).

TTB notes that, because the southern portion of the proposed Big Valley District–Lake County boundary abuts the northern portion of the proposed Kelsey Bench–Lake County viticultural area boundary, if the two proposed viticultural areas are established, this shared boundary line would split two vineyards between the two viticultural areas. However, the petition included letters from both vineyard owners stating their understanding of the potential split and their support for the establishment of both of the proposed viticultural areas.

The petitioner also requested a modification of a small portion of the western boundary of the established ''Red Hills Lake County'' viticultural area (27 CFR 9.169), to align it with the eastern boundary of the proposed Kelsey Bench–Lake County viticultural area using features identifiable on the newest version of the USGS map. The proposed boundary modification is discussed later in this document.

Big Valley District–Lake County

The proposed Big Valley District–Lake County viticultural area contains approximately 11,000 acres located south of the southern shore of Clear Lake in northern California. There are 6 wineries within the proposed viticultural area, as well as 43 commercially-producing vineyards covering approximately 1,800 acres. The petition states that the distinguishing features of the proposed viticultural area are geology, soils, climate, and topography.

Name Evidence

The name ''Big Valley'' has been associated with the region of the proposed viticultural area since the mid-19th Century, appearing in the 1870 Federal Census as a district within Lake County, California. As evidence of the usage of the proposed name, the petitioner references an historical account of the settlement of Napa and Lake Counties, published in 1881, which notes that ''Big Valley is the garden spot of Lake County,'' and that ''small fruits and berries thrive here

also, as do grapes.'' (*History of Napa and Lake Counties, California.* Slocum, Bowen, & Co., Publishers, 1881.) The petitioner references another book, published in the 1880s, which includes a section called ''Big Valley'' in a chapter titled ''Lakeport and Its Surroundings.'' (*A Description of Lake County,* published by Authority of the Board of Supervisors, 1888.) In addition, the region within the proposed viticultural area also gives its name to the Big Valley Band of the Pomo Indians, a tribe native to the region of the proposed viticultural area. The Big Valley Rancheria, which is currently home to members of the tribe, is located within the proposed viticultural area.

The name ''Big Valley'' also appears on numerous maps in association with the region of the proposed viticultural area. A 1927 map produced by the United States Department of Agriculture's Bureau of Chemistry and Soils, as well as the 1989 soil survey map of Lake County, California, published by the USDA Soil Conservation Service both show a region marked as ''Big Valley'' on the southern shore of Clear Lake. Additionally, the United States Geological Survey (USGS) maps for the Kelseyville, Lucerne, and Highland Springs quadrangles all refer to the region of the proposed viticultural area as ''Big Valley.''

The petition included several other examples of evidence that indicate the region of the proposed viticultural area is known as ''Big Valley.'' The Lake County Winegrape Growers Web site refers to Big Valley as a winegrape growing region and notes that ''Big Valley growers were among the first visionaries to discover the region's winegrape potential * * *.'' (See *www.lakecountywinegrape.org.*) The USGS Kelseyville quadrangle map features a road named ''Big Valley Road'' that runs through the proposed viticultural area. Additionally, the AT&T Yellow Pages for Lake and Mendocino Counties lists several businesses within the proposed viticultural area that use the name ''Big Valley,'' including Big Valley Electric, Big Valley Truck and Auto Repair, and Big Valley Properties.

TTB notes that the USGS Geographic Names Information System (GNIS) lists 98 entries for ''Big Valley'' and variations of the name, including 22 listings for schools, churches, populated places, and locales in Lassen, Modoc, Calaveras, Placer, Stanislaus, and San Joaquin Counties in California, as well as in Lake County. Because there are multiple locations known as ''Big Valley'' throughout the United States, the petitioner included the modifier ''Lake County'' in the proposed name to distinguish the proposed viticultural area. Additionally, the petitioner stated that the use of the ''Lake County'' modifier would conform to the naming convention started by the neighboring Red Hills Lake County viticultural area. TTB notes that the GNIS lists a valley named Big Valley in Lake County, Oregon. However, because there is no commercial viticulture within Lake County, Oregon, TTB believes that there would not be a risk of consumer confusion if the proposed Big Valley District–Lake County viticultural area is established.

Boundary Evidence

The proposed Big Valley District–Lake County viticultural area is a bowl-shaped valley located in central Lake County, California, within the established Clear Lake viticultural area. The proposed viticultural area sits at approximately 1,360 feet above sea level and has a generally flat topography that gently slopes downward to the north towards Clear Lake, which forms its northern boundary.

The 1,400-foot elevation contour line and a small portion of Cole Creek form the eastern portion of the proposed boundary. The proposed boundary separates the low, flat valley of the proposed viticultural area from the high, steep elevations of Mount Konocti, to the east, and the Red Hills, to the southeast.

A series of roads, a portion of Hill Creek, and the 1,400-foot elevation contour line make up the southern portion of the proposed boundary. To the south of this boundary is the proposed Kelsey Bench–Lake County viticultural area, which is marked by river terraces and benches, as compared to the relatively flat topography of the proposed Big Valley District–Lake County viticultural area.

The western portion of the proposed boundary follows a series of roads that lead to Thompson Creek. The boundary then follows Thompson Creek to the point where it empties into Clear Lake. This portion of the proposed boundary separates the lower, flatter valley of the proposed viticultural area from the higher, steeper terrain of the Mayacmas Mountains to the west.

Distinguishing Features

The distinguishing features of the proposed Big Valley District–Lake County viticultural area are its geology, soils, climate, and topography. Because the proposed viticultural area is bordered by Clear Lake to the north and to the south by the proposed Kelsey Bench–Lake County viticultural area, which is discussed later in this document, the following sections only contrast the distinguishing features of the proposed Big Valley District–Lake County viticultural area with the regions to the east and west.

Geology

During the Jurassic period, approximately 135 million years ago, Lake County was covered by water. About 3 million years ago, side-by-side ''strike-slip'' movement of tectonic plates along the San Andreas Fault warped the layers of rock on the lake bed and began forming structural basins underneath the water, including the structural basin that comprises the proposed Big Valley District–Lake County viticultural area. The region of the proposed Big Valley District–Lake County viticultural area remained underwater until approximately 460,000 years ago, when Mount Konocti was formed. As the mountain rose, it forced the landmass known today as Big Valley to rise above the surface. When the Big Valley landmass rose, it brought with it the sedimentary lake bed deposits that eventually formed the deep, nutrient-rich soil desired by vineyard owners.

The two major geological units of the proposed viticultural area—the Franciscan Complex and Great Valley sequence—formed through subduction, the process of one tectonic plate sliding beneath another. The formations are comprised of chert, greywacke, shale, metasedimentary rocks, and metavolcanic rocks thrown together as the two plates collided. The weathering of these rocks contributes to the soil nutrient content and soil pH levels within the proposed viticultural area, which affect vine growth and fruit development.

Three fault lines that are part of the San Andreas Fault system run beneath the proposed Big Valley District–Lake County viticultural area: The Big Valley Fault, the Adobe Creek Fault, and the Wight Way Fault. The ''strike-slip'' movement of these faults throughout the ages has contributed to the gentle northerly downward slope of the basin. The basin shape of the proposed viticultural area and its gentle slope contribute to airflow patterns which cool and dry the vineyards, reducing stress on the vines. Additionally, the nearly level terrain within the basin reduces the risk of soil erosion within the proposed viticultural area.

To the east of the proposed viticultural area, the geology is dominated by Mount Konocti, a dormant volcano. This mountain is part of the Clear Lakes Volcanics formed in

the middle Pliocene Epoch. The rocks are composed of basalt, rhyolite, and other volcanic materials.

The region to the west of the proposed viticultural area is comprised of the Mayacmas Mountains and the uplifted hills and terraces that form their foothills. Rocks of the Franciscan Complex are present, as within the proposed viticultural area, but geological forces have lifted this region high above the valley to form steep and rugged mountains.

Soils

The soils of the proposed Big Valley District–Lake County viticultural area have lacustrine (freshwater lake) and alluvial (eroded and re-deposited by moving water) origins. Soil pH levels range from a slightly acidic 6.0 to a mildly alkaline 7.5 which, according to the petition, is within the optimal range for nutrient uptake by the grapevines. The soil drainage is poor by nature but has been improved through artificial means. There is little risk of soil erosion within the proposed viticultural area due to the nearly level topography of the valley.

Major soil series within the proposed Big Valley District–Lake County viticultural area include Cole clay loam, Clear Lake clay, and Still loam, which together make up approximately 75 percent of the soil within the proposed viticultural area. These soils are generally deep, which allows for good rooting. However, in some locations within the proposed viticultural area, these soils also have ''limiting factors,'' such as hardpan, rocks, or clay substrata, which prevent the roots from penetrating further. Additionally, Clear Lake clay is a high ''shrink-swell'' clay soil that forms deep cracks when it dries during summer months. The shrinking and cracking of the dried soil can sever the roots of the vines and prevent them from reaching deep into the soil. Factors that limit root depth can be beneficial to grape growers, according to the petition, preventing excessive foliage growth and producing small grapes that have a desirable concentration of flavors and colors.

East of the proposed Big Valley District–Lake County viticultural area, the soils are primarily of the Konocti-Benridge series. The soils are formed from volcanic materials such as andesite, basalt, dacite, and pyroclastic tuff. To the west of the proposed viticultural area, the soils are of the Wappo series. Wappo soils are less fertile than the soils within the proposed viticultural area, although they are naturally better drained than the clay and loam soils of the proposed viticultural area. The soils to both the east and west of the proposed viticultural area are generally shallower due to the steeper terrain and are at a greater risk of erosion than the soils of the valley.

Climate

The petition to establish the proposed Big Valley District–Lake County viticultural area included information on the wind, growing degree days, frost-free days, and precipitation within the proposed viticultural area and the surrounding regions.

Wind: The winds within the proposed Big Valley District—Lake County viticultural area are influenced by the region's proximity to both Clear Lake and the higher elevations of the neighboring Mayacmas Mountains, Red Hills, and Mount Konocti. Water in Clear Lake warms more slowly than the adjacent land during the day and also holds its heat longer at night. At night, the cool air in the mountains becomes heavy and sinks into the lower elevations. As it flows across the lake, the air is warmed by the heat being slowly released from the water. The warmed air becomes less dense and rises, pulling more of the cooler, heavier air from the shore and creating south-north breezes that blow towards the lake. During the day, the land becomes warmer than the lake, reversing the process and causing north-south winds that blow towards the shore.

The following table shows the average wind speeds gathered from two weather stations within the proposed Big Valley District—Lake County viticultural area (Bell Hill West and Kelseyville). The data was collected from 2008 through 2010.

BIG VALLEY WIND SPEEDS

	Bell Hill West (mph)	Kelseyville (mph)
2008	3.59	3.17
2009	3.47	3.18
2010	3.40	3.28
Average wind speed	3.48	3.21

According to the petition, the winds within the proposed viticultural area are strong enough to reduce heat stress on the vines and to remove excess moisture that promotes mildew. However, they are not strong enough to damage leaves or buds, nor are they strong enough to force the stoma on the leaves to close. When the stoma on the leaves close, the vines do not photosynthesize efficiently and fruit ripens more slowly.

To the east and southeast of the proposed Big Valley District—Lake County viticultural area, on Mount Konocti and in the Red Hills, the winds are also influenced by both the lake and the slopes of the mountains. However, a diagram produced by the Lake County Air Pollution Control District included with the petition suggests that the winds in the Red Hills and Mount Konocti blow in a west-east direction, as they are channeled around the ridges and peaks of the rugged terrain. The average wind speeds shown on the diagram also suggest the winds to the east and southeast of the proposed viticultural area are stronger, especially in the afternoon, with speeds ranging up to 10 miles per hour. Winds of this strength stimulate the stoma of the leaves to close and can damage leaves and buds.

Temperature: The table below compares the number of growing degree days (GDDs) [1] from three weather stations within the proposed viticultural area to three stations located in the established Red Hills Lake County viticultural area, to the southeast. According to the petition, weather station data is not available for the region immediately west of the proposed viticultural area, and recent temperature data was also not available

[1] In the Winkler climate classification system, annual heat accumulation during the growing season, measured in annual GDD, defines climatic regions. One GDD accumulates for each degree Fahrenheit that a day's mean temperature is above 50 degrees, the minimum temperature required for grapevine growth (''General Viticulture,'' by Albert J. Winkler, University of California Press, 1974, pages 61–64).

from the Lakeport weather station to the northwest of the proposed viticultural area.

northwest of the proposed viticultural area.

GROWING DEGREE DAY TOTALS

Year	Big Valley District—Lake County stations			Red Hills Lake County AVA stations		
	Kelseyville	Kelseyville South	Bell Hill West	Red Hills 1	Red Hills 2	Red Hills 3
2005	2623	2911	2958	3343	N/A	3298
2006	3080	3317	3303	3826	3718	3769
2007	2805	3110	3042	3571	3397	3472
2008	3036	3304	3285	3917	3790	3953
2009	3038	3249	3237	3805	3690	3789
2010	2683	2851	2837	3256	3126	3246
Average	2878	3124	3110	3620	3544	3588

According to the data, the proposed Big Valley District—Lake County viticultural area has fewer annual GDDs than the Red Hills Lake County viticultural area, indicating cooler temperatures within the proposed viticultural area. The number of GDDs for the proposed viticultural area classifies it as a high Region II or low Region III on the Winkler classification scale. The Red Hills Lake County viticultural area, by contrast, has enough GDDs to classify it as a Region IV area. The GDDs of an area play a role in determining the varieties of grapes that are best suited for planting. The cool climate of the proposed viticultural area is suitable for growing Sauvignon Blanc, which is one of the more cultivated grape varieties within the proposed viticultural area but is not grown as commonly in the surrounding regions.

The cooler temperatures also results in fewer frost-free days within the proposed Big Valley District—Lake County viticultural area as compared to the region to the east, within the Red Hills Lake County viticultural area. The table below shows the frost-free dates for three stations within the proposed viticultural area and three stations within the established Red Hills Lake County viticultural area during 2008 and 2009.

FROST FREE DAYS

	Big Valley District—Lake County stations			Red Hills Lake County AVA stations		
	Kelseyville	Kelseyville South	Bell Hill West	Red Hills 1	Red Hills 2	Red Hills 3
2008						
Latest frost date	May 1	May 1	May 1	April 24	April 24	April 24.
Earliest frost date	October 11	October 10	October 10	December 13	December 13	December 13.
Frost-free days	162	161	161	232	232	232.
2009						
Latest frost date	April 16	April 29	April 29	April 14	April 15	April 15.
Earliest frost date	September 30	September 30	October 4	November 19	November 19	December 6.
Frost-free days	166	153	157	218	217	234.

The first fall frosts occur earlier within the proposed viticultural area, and the last spring frosts occur later. The longer frost periods can be attributed to cool air drainage. At night, cooler, heavier air drains off the higher elevations of the Red Hills Lake County viticultural area and pools in the lower elevations of the proposed viticultural area, cooling the valley temperatures and increasing the risk of frost, while allowing for warmer temperatures in the mountains and hills.

The number of frost-free days in an area can determine the types of grapes that can be grown. Early frosts can damage vines and fruits and prevent the fruits from ripening or developing the necessary sugars for successful wine development. Spring frosts that occur after bud break can cause the young shoots to die and reduce fruit yields. Therefore, growers study the frost patterns within their region in order to choose grape varieties that can ripen successfully before frost occurs and that do not begin to produce buds until after frosts are no longer a threat.

Precipitation: Precipitation levels in the proposed Big Valley District—Lake County viticultural area differ from those of the surrounding area. The proposed viticultural area is surrounded by higher elevations to the west (Mayacmas Mountains), south (proposed Kelsey Bench—Lake County viticultural area), and east and southeast (Mount Konocti and the Red Hills). As rain-bearing clouds approach the proposed viticultural area, the clouds drop most of their rain as they rise over the mountains and hills, leaving less rain to fall in the valley.

The following table illustrates the differences in annual precipitation averages between the three weather stations within the proposed viticultural area (Kelseyville, Kelseyville South, and Bell Hill West) and three weather stations within the established Red Hills Lake County viticultural area (Red Hills 1, 2, and 3) to the east.

AVERAGE ANNUAL RAINFALL (INCHES)

Year	Proposed viticultural area	Red Hills Lake County AVA
2008	15.4	25.42
2009	14.8	22.46
2010	31.5	44.96
Average annual rainfall	20.6	37.8

The data in the table shows the higher elevations of the established Red Hills Lake County viticultural area receive more annual rainfall than the lower elevations of the proposed viticultural area. Rainfall plays a critical role in ensuring sufficient water for irrigation of grapevines and recharging the underlying groundwater, but high amounts of rainfall promote soil erosion in regions with steep terrain and cause mildew or root rot in poorly-drained soils.

Annual rainfall amounts also distinguish the proposed Big Valley District—Lake County viticultural area from the proposed Kelsey Bench—Lake County viticultural area to the south, which is discussed later in the document. Precipitation amounts for the region to the immediate west of the proposed viticultural area are not available but the petition states that one can expect rainfall patterns to be greater in the higher elevations of the Mayacmas Mountains to the west than within the lower elevations of the proposed Big Valley District—Lake County viticultural area.

Topography

The proposed viticultural area is a bowl-shaped valley with an average elevation of approximately 1,360 feet. With slopes of less than 2.5%, the terrain is almost completely flat, tilting gently downward to the north towards Clear Lake. Higher, steeper elevations are found to the east and west of the proposed viticultural area, as shown on USGS maps. To the east, Mount Konocti reaches a height of 4,300 feet. To the west, the Mayacmas Mountains rise to 3,320 feet at Monument Peak. The low, flat topography of the proposed viticultural area allows cold air draining from the higher surrounding elevations to pool in the valley, as previously discussed, and also contributes to lower annual rainfall amounts and lower risk of soil erosion than in the surrounding regions.

Kelsey Bench—Lake County

The proposed Kelsey Bench—Lake County viticultural area contains approximately 9,100 acres immediately south of the proposed Big Valley—Lake County viticultural area. There are 27 vineyards covering over 900 acres, in addition to one winery. The petition states that the distinguishing features of the proposed viticultural area are geology, soils, climate, and topography.

Name Evidence

The proposed name ''Kelsey Bench'' is a combination of ''Kelsey,'' the surname of several early settlers in the area, and ''bench,'' a term used to describe the terraces that rise above the lower elevations of the valley to the north and extend south and east towards the Mayacmas Mountains and the Red Hills.

The name ''Kelsey'' appears as part of the names of a town, a road, a creek, and several businesses within the proposed viticultural area. The town of Kelseyville is partially located within the proposed viticultural area and appears on the USGS Kelseyville quadrangle map. A creek identified as Kelsey Creek and a road marked as Kelsey Creek Drive also both appear on the USGS Kelseyville quadrangle map within the boundaries of the proposed viticultural area. Finally, the Real Yellow Pages for Lake and Mendocino Counties lists ''Kelsey Creek Storage,'' ''Kelseyville Lumber,'' and ''Kelseyville Appliance'' as businesses within the proposed viticultural area.

The name ''Kelsey Bench'' also appears on several wine-related Web sites in reference to the region of the proposed viticultural area. The Lake County Winegrape Growers Web page (*www.lakecountywinegrape.org*) features a regional profile page for ''Kelsey Bench.'' The Web page for the Rosa d'Oro Vineyard (*www.rosadorowine.com*), located within the proposed viticultural area, describes the vineyard's ''well-drained Kelsey Bench soil,'' and the Catspaw Vineyard, located within the proposed viticultural area, notes on its Web page that, ''Kelsey Bench has a mix of gravel, clay, and loam soils * * *.'' (*www.northcoastwinegrapes.com/growers/catspaw.pdf*). Finally, the North Coast Winegrape Brokers Web page (*www.northcoastwinegrapes.com/growers/grapes-for-sale.php*) listing of 2010 wine grapes and bulk wine for sale includes several entries for Cabernet Franc, Chardonnay, and Merlot grapes and wines from vineyards and wineries in ''Kelsey Bench.''

The petition notes that a variant of the proposed name, ''Kelseyville Bench,'' is often used in relation to the proposed viticultural area. However, the petitioners chose not to propose the name ''Kelseyville Bench'' because the name could imply the town of Kelseyville was located entirely within the proposed viticultural area. Only a small portion of the town is within the proposed viticultural area, while the rest of the town is within the boundary of the proposed Big Valley District—Lake County viticultural area. Therefore, to avoid potential confusion, the petitioners proposed the name ''Kelsey Bench.''

Boundary Evidence

The proposed Kelsey Bench—Lake County viticultural area is located in central Lake County, California, within the established Clear Lake viticultural area. Elevations within the proposed viticultural area range between approximately 1,400 and 1,600 feet. The proposed viticultural area is bordered to the north by the proposed Big Valley District—Lake County viticultural area, to the east by Mount Konocti and the Red Hills, and to the south and west by the Mayacmas Mountains.

A series of roads, a portion of Hill Creek, and the 1,400-foot elevation contour line form the northern portion of the proposed boundary. This border separates the proposed Kelsey Bench—Lake County viticultural area from the lower, nearly level terrain of the proposed Big Valley District—Lake County viticultural area to the north.

A series of roads and the 1,600-foot elevation contour line forms the eastern portion of the proposed boundary. A portion of this proposed boundary is also shared with the existing Red Hills Lake County viticultural area. The proposed boundary separates the proposed Kelsey Bench—Lake County viticultural area from the steeper, higher

elevations of Mount Konocti and the Red Hills.

The southern portion of the proposed boundary follows the 1,600-foot elevation contour line and a series of roads. To the south of the proposed boundary is the high, steep terrain of the Mayacmas Mountains.

A series of roads and the 1,600-foot elevation contour line forms the western portion of the proposed boundary. Immediately adjacent to the northwest portion of this boundary is the Highland Springs Reservoir. Although the terrain surrounding the reservoir is similar to that of the proposed viticultural area, the petition states that this land was excluded because it is public park land and is thus unlikely to be available for commercial viticulture. Immediately to the west and southwest of the reservoir are the steeper, higher elevations of the Mayacmas Mountains.

Distinguishing Features

According to the petition, the distinguishing features of the proposed Kelsey Bench—Lake County viticultural area are geology, soils, climate, and topography.

Geology

Three faults that are part of the San Andreas Fault system run beneath the proposed Kelsey Bench—Lake County viticultural area: The Big Valley Fault, the Wight Way Fault, and the Adobe Creek Fault. At various times throughout history, the movement of these three faults, along with the San Andreas Fault, has uplifted the region and contributed to the terraced landscape within the proposed viticultural area. The terraces and benches of the proposed viticultural area reduce the risk of frost within the proposed viticultural area because cold air drains off the terraces at night and into the lower, flatter valley to the north, outside the proposed viticultural area.

The Kelseyville Formation is a major geological feature of the proposed Kelsey Bench—Lake County viticultural area. The formation was created during the middle Pleistocene era, between approximately 780,000 and 126,000 years ago, and consists mainly of sandstone, siltstone, and mudstone. Below the formation are rocks of the Franciscan Complex and flows of the Clear Lake volcanic field; above the formation are Quaternary terrace deposits. The Kelseyville Formation contains two volcanic ash aquifers which serve as the water resources of the area. The ''ash'' consists of angular fragments of volcanic rock ranging from the size of a grain of sand to the size of pea gravel. These fragments are quite permeable and allow water from stream courses and saturated confining strata to leak into and recharge the aquifers, providing a source of water for irrigating the vineyards within the proposed viticultural area.

To the north of the proposed Kelsey Bench—Lake County viticultural area is the proposed Big Valley District—Lake County viticultural area. The geology of the proposed Big Valley District—Lake County viticultural area is comprised of two major geological units—the Franciscan Complex and the Great Valley sequence. The Big Valley, Wight Way, and Adobe Creek Faults also run beneath the proposed Big Valley District—Lake County viticultural area, where the movement of the faults over the ages has gently tilted the valley downward towards Clear Lake.

To the east and northeast of the proposed Kelsey Bench—Lake County viticultural area are Mount Konocti and the established Red Hills Lake County viticultural area. Both regions are part of the Clear Lake Volcanics, formed in the middle Pliocene Epoch, and have rocks composed of basalt, rhyolite, and other volcanic materials.

The Mayacmas Mountains lie to the south and west of the proposed Kelsey Bench—Lake County viticultural area. The mountain range is comprised of rock from the Mesozoic era that is much older than the Kelseyville Formation. The rocks consist mainly of sandstone, conglomerate, and argillite, with smaller amounts of greenstone, chert, limestone, and blueschist.

Soils

The soils of the proposed Kelsey Bench—Lake County viticultural area were shaped over time by the forces of geology, water, and weather. Three general soil map units are found extensively within the proposed viticultural area: the Manzanita—Wappo—Forbesville unit (MWF), which comprises approximately 31% of the soils within the proposed viticultural area; the Phipps—Bally unit (PB), which accounts for approximately 26% of the soils; and the Millsholm—Skyhigh—Bressa (MSB) unit, which comprises approximately 14% of the soils. MWF and PB soils are very deep and well drained and formed in alluvium. MSB soils are shallow to moderately deep and are formed from sandstone, shale, and siltstone.

Most of the vineyards within the proposed viticultural area are planted on soils of the MWF general soil map unit, a fact the petition attributes to the relatively milder slopes of soils associated with this unit, as well as the greater presence of the MWF soils within the proposed viticultural area. MWF soils are acidic, with pH levels between 5.0 and 6.5. The acidity in the soils allows for nutrient uptake by the vines but is low enough to prevent the vines from absorbing nutrients at levels that could become damaging to the plant. Clay accumulates at depths of 16 to 70 inches, which limits root depth and prevents vines from growing too vigorously. MWF soils are low in fertility, which, according to the petition, provides lean conditions that result in grapes with high concentrations of flavor, although the yields may be lower than those of vineyards planted on more fertile soil.

To the north, in the proposed Big Valley District—Lake County viticultural area, 75 percent of the soils are of the Cole clay loam, Clear Lake clay, and Still loam series. By contrast, these soil series comprise only 10 percent of the proposed Kelsey Bench—Lake County viticultural area soils. The MWF, MSB, and PB soils that comprise over 70 percent of the proposed Kelsey Bench—Lake County viticultural area soils are not found in the area to the north. Additionally, the soils in the area to the north are slightly less acidic than those within the proposed Kelsey Bench—Lake County viticultural area.

To the east, the soils of the established Red Hills Lake County viticultural area are composed of Glenview—Bottlerock—Arrowhead, Konocti—Benridge, and Collayomi—Aiken soil types. These soils are formed from volcanic materials such as andesite, basalt, dacite, and pyroclastic tuff and have significant gravel content.

To the south and west, the soils of the Mayacmas Mountains are in the Maymen—Etsel and Henneke—Okiota—Montara general soil map units. These soils are characterized by shallow depths and moderate to severe erosion potential. The Maymen—Etsel soils are derived from graywackes and sandstone while the Henneke—Okiota—Montara soils are predominately derived from weathered serpentine rock.

Climate

The petition to establish the proposed Kelsey Bench—Lake County viticultural area included information on the wind, growing degree days, frost-free days, and precipitation for the proposed viticultural area. Climate data was not available for the Mayacmas Mountains region to the south and west of the proposed viticultural area.

Wind: The petition states that there is only one official weather station located within the proposed Kelsey Bench—Lake County viticultural area, on the

Silva Ranch in the northern portion of the proposed viticultural area. However, only partial wind data from 2011 was available at the time the petition was submitted. Therefore, the petition included testimony from growers concerning the winds within the proposed viticultural area and contrasting them to the winds within the proposed Big Valley District—Lake County viticultural area.

The petition included testimony from the owner of Eutenier Ranches, who has vineyards both within the proposed Kelsey Bench—Lake County viticultural area and in the proposed Big Valley District—Lake County viticultural area to the north. The owner notes that the summer winds in the vineyard in the proposed Kelsey Bench—Lake County viticultural area can become so strong that the stomata on the grape leaves close, reducing photosynthesis and delaying the ripening of fruit. As a result, his grapes within the proposed Kelsey Bench—Lake County viticultural area usually have a later harvest date than those in his vineyard within the proposed Big Valley District—Lake County viticultural area, even though both vineyards are planted with the same variety of grapes.

A second grower who had resided at the Silva Ranch within the proposed Kelsey Bench—Lake County viticultural area for six years and who also had vineyards within the proposed Big Valley District—Lake County viticultural area also provided testimony. This grower confirms the strong winds within the proposed Kelsey Bench—Lake County viticultural area. The grower also notes that the winds within the proposed Kelsey Bench—Lake County viticultural area begin earlier in the day than within the proposed Big Valley District—Lake County viticultural area. The grower notes that he could have workers spraying crops on his property in the proposed Big Valley District—Lake County viticultural area in the late morning, whereas the winds would already be too strong in the proposed Kelsey Bench—Lake County viticultural area to spray crops safely and effectively.

Temperature: The temperatures in the proposed Kelsey Bench—Lake County viticultural area are generally warmer than those of the proposed Big Valley District—Lake County viticultural area to the north and cooler than those of the existing Red Hills Lake County viticultural area to the east.

The petition states that current growing degree day (GDD) data is not available from the one official weather station located within the proposed Kelsey Bench—Lake County viticultural area. However, the petition did include a discussion of GDD totals from Arkley Vineyards for the period from 1999—2002.[2] Arkley Vineyards is located within the proposed Kelsey Bench—Lake County viticultural area. According to the petition, the average annual GDD total for Arkley Vineyards was 3,225, which is greater than the 3,037 average annual GDD total for the proposed Big Valley District—Lake County viticultural area. To the east in the established Red Hills Lake County viticultural area, the average GDD total from the three weather stations for the period from 2005 to 2010 was 3,584.

In comparison to the proposed Big Valley District—Lake County viticultural area, the proposed Kelsey Bench—Lake County viticultural area has warmer daytime temperatures and a longer frost-free period. Temperature data was collected from the Silva Ranch weather station throughout 2011 and compared to data from weather stations within the proposed Big Valley District—Lake County viticultural area. The data shows that each month had a minimum of 13 days where temperatures within the proposed Kelsey Bench—Lake County viticultural area were higher than within the proposed Big Valley District—Lake County viticultural area, for a total of 283 days with warmer temperatures.

With respect to the frost-free period, the petition gathered temperature data from the Silva Ranch weather station and from three weather stations within the proposed Big Valley District—Lake County viticultural area during 2011. The table below shows the total number of frost-free days as well as the earliest freeze dates for each weather station.

FROST FREE DAYS

Location	Kelseyville South	Kelseyville	Bell Hill West	Silva Ranch
Earliest frost date	October 26	October 27	October 26	November 3.
Frost-free days	179	180	178	187.

The proposed Kelsey Bench—Lake County viticultural area petition did not include 2011 frost data from the region to the east, within the established Red Hills Lake County viticultural area. However, information from 2008 and 2009 was provided in the Big Valley District—Lake County petition and was described in the temperature section of the proposed Big Valley District—Lake County viticultural area discussion portion of this document. That information showed the Red Hills area has an average of 227 frost-free days, longer than that of the proposed Kelsey Bench—Lake County viticultural area. The Red Hills region also averaged a later first frost date than the proposed Kelsey Bench—Lake County viticultural area.

The length of the frost-free period within the proposed Kelsey Bench—Lake County viticultural area affects the grape varieties grown. According to the petition, the temperatures make the proposed viticultural area suitable for growing red varieties such as Merlot, Cabernet Sauvignon, and Zinfandel. The longer growing season also provides a longer time for the grapes to ripen, which can compensate for the slower ripening conditions that the windy conditions within the proposed viticultural area create.

Precipitation: Precipitation levels in the proposed Kelsey Bench—Lake County viticultural area are generally greater that those within the proposed Big Valley District—Lake County viticultural area. The table below shows annual precipitation amounts measured by two property owners within the proposed Kelsey Bench—Lake County viticultural area and three weather stations within the proposed Big Valley District—Lake County viticultural area. Each data collection period began on

[2] The GDD data for Arkley Vineyards was originally part of a comment submitted in response to the 2002 notice of proposed rulemaking to establish the Red Hills Lake County viticultural area (October 30, 2002, 67 FR 66083). The commenter included climate and soil data from his Arkley Vineyards as part of his request to extend the boundary of the Red Hills Lake County viticultural area to include approximately 2,000 acres to the southwest of the viticultural area. The request to include the region as part of the Red Hills Lake County viticultural area was ultimately rejected. The region described in the comment is currently included in the proposed Kelsey Bench—Lake County viticultural area.

July 1 and ended on June 30 of the following year.

PRECIPITATION TOTALS FOR PROPOSED KELSEY BENCH—LAKE COUNTY AND BIG VALLEY DISTRICT—LAKE COUNTY VITICULTURAL AREAS

Time Period	Proposed Big Valley District—Lake County Viticultural Area			Proposed Kelsey Bench—Lake County Viticultural Area	
	Kelseyville	Kelseyville South	Bell Hill West	Bell Hill Lane	Boggs Lane
2007–2008	18.33	14.65	13.22	N/A	29.4
2008–2009	16.23	13.09	15.07	18.75	21.6
2009–2010	29.22	31.81	33.43	31.25	39.2

Topography

The topography of the proposed Kelsey Bench—Lake County viticultural area is comprised of uplifted dissected terraces or benches, plateaus, and gently rolling hills, with elevations ranging from 1,400 feet at the northern boundary to 1,600 feet near the southern boundary. The topography was formed over time by the movement of the faults beneath the proposed viticultural area, which raised the ground to form the benches and hills. The continued uplifting of the terrain due to fault movement has been recorded as recently as 1906, when a major earthquake along the San Andreas Fault altered the Kelseyville Formation that underlies the proposed viticultural area, uplifting and dissecting portions along the southeastern portion of the proposed viticultural area.

The slopes and terraces allow cool air to drain away from the proposed viticultural area at night and into the lower elevations of the neighboring proposed Big Valley District—Lake County viticultural area. Although cool air does drain into the proposed Kelsey Bench—Lake County viticultural area from the higher elevations of the surrounding Mayacmas Mountains and Red Hills, most of the cool air does not pool in the proposed viticultural area but instead continues to drain into the even lower elevations of the proposed Big Valley District—Lake County viticultural area. Because most of the cool nighttime air does not settle in the slopes and benches of the proposed Kelsey Bench—Lake County viticultural area, the frost damage to vines and fruit in the early spring and fall is reduced. As evidence of the reduced frost within the proposed Kelsey Bench—Lake County viticultural area, the petitioner provided testimony from the University of California Viticulture and Plant Science Advisor for Mendocino and Lake Counties. The advisor states that due to the reduced frost within the proposed Kelsey Bench—Lake County viticultural area, many vineyards do not have overhead sprinklers for frost protection, but such protection ''is a necessity'' for vineyards in the proposed Big Valley District—Lake County viticultural area.

Summary of Distinguishing Features of the Proposed Viticultural Areas

The proposed Big Valley District—Lake County and Kelsey Bench—Lake County viticultural areas differ from each other and from the surrounding regions in terms of topography, geology, soils, and climate. The table below provides a summary of the general characteristics of both proposed viticultural areas in comparison to the surrounding regions. Because Clear Lake sits to the north of both proposed viticultural areas, the features of the area to the north are not included in this table.

Area	Description
Proposed Big Valley District—Lake County AVA	Generally level land with elevations at about 1,350 feet; younger soils formed from lacustrine and alluvial materials; cool temperatures due to proximity to lake and cool air draining from surrounding higher elevations; vineyards primarily grow sauvignon blanc grapes.
Proposed Kelsey Bench—Lake County AVA	Bench lands and terraces with elevations from 1,400 to 1,600 feet; older soils formed from alluvial materials; warm temperatures due to cool air draining into lower neighboring valley; vineyards primarily grow red varieties such as cabernet sauvignon, merlot, and zinfandel.
To the East (Red Hills, Mt. Konocti)	Steep mountains with elevations up to 4,300 feet; soils of volcanic origin; warmer temperatures and more frost-free days than both proposed AVAs.
To the South and West (Mayacmas Mountains)	Steep mountains with elevations up to 3,320 feet; shallow soils derived from graywackes, sandstone, and serpentine rocks.

Comparison of the Proposed Big Valley District—Lake County and Kelsey Bench—Lake County Viticultural Areas to the Existing Clear Lake and North Coast Viticultural Areas

Clear Lake Viticultural Area

The proposed Big Valley District—Lake County and Kelsey Bench—Lake County viticultural areas lie entirely within the Clear Lake viticultural area and, together, cover approximately 11 percent of the larger established viticultural area. The Clear Lake viticultural area was established by T.D. ATF–174, which published in the **Federal Register** on May 8, 1984 (49 FR 19468) and is located within Lake County, California. T.D. ATF–174 describes the Clear Lake viticultural area as 168,960 acres of valley and upland terrain rimmed by steep mountains. At the center of the viticultural area is the large freshwater lake known as Clear Lake. The lake has a moderating influence on temperatures in the area, warming the air in the winter and cooling it in the summer. Rainfall in the Clear Lake viticultural area averages 37 inches annually and the growing season averages 223 days.

The information provided in the petitions shows that the smaller

proposed Big Valley District—Lake County and Kelsey Bench—Lake County viticultural areas have general characteristics similar to those of the Clear Lake viticultural area. Both proposed viticultural areas are at lower elevations than the Mayacmas Mountains that also border the Clear Lake viticultural area. Additionally, the climate of both proposed viticultural areas is influenced by Clear Lake, with the lake providing a source of cooling breezes that keep temperatures moderate. However, TTB notes that each of the two proposed viticultural areas has a more uniform topography than that of the larger Clear Lake viticultural area. The proposed Big Valley District—Lake County viticultural area is a low, level, basin-shaped valley that lacks upland terrain. The proposed Kelsey Bench—Lake County viticultural area consists of terraces and gently rolling hills and lacks large, level expanses of land. Additionally, the average growing season is slightly shorter than the overall average growing season length within the larger Clear Lake viticultural area.

North Coast Viticultural Area

The North Coast viticultural area was established by T.D. ATF–145, which was published in the **Federal Register** on September 21, 1983 (48 FR 42973). It includes all or portions of Napa, Sonoma, Mendocino, Solano, Lake, and Marin Counties, California. TTB notes that the North Coast viticultural area contains all or portions of approximately 40 established viticultural areas, in addition to the area covered by the proposed Big Valley District—Lake County and Kelsey Bench—Lake County viticultural areas. In the conclusion of the ''Geographical Features'' section of the preamble, T.D. ATF–145 states that ''[d]ue to the enormous size of the North Coast, variations exist in climatic features such as temperature, rainfall, and fog intrusion.''

The proposed Big Valley District—Lake County and Kelsey Bench—Lake County viticultural areas share several basic viticultural features of the North Coast viticultural area—moderate growing season temperatures that are cooler than the temperatures in the Central Valley farther inland, and flat valleys and tillable hillsides surrounded by mountains. However, the proposed viticultural areas are much more uniform in their geography, geology, climate, and soils than the diverse multicounty North Coast viticultural area. In this regard, TTB notes that T.D. ATF–145 specifically states that ''approval of this viticultural area does not preclude approval of additional areas, either wholly contained with the North Coast, or partially overlapping the North Coast,'' and that ''smaller viticultural areas tend to be more uniform in their geographical and climatic characteristics, while very large areas such as the North Coast tend to exhibit generally similar characteristics, in this case the influence of maritime air off of the Pacific Ocean and San Pablo Bay.'' Thus, the proposal to establish the Big Valley—Lake County and Kelsey Bench—Lake County viticultural areas is not inconsistent with what was envisaged when the North Coast viticultural area was established.

Proposed Boundary Modification of the Established Red Hills Lake County Viticultural Area

The Red Hills Lake County viticultural area was established by T.D. TTB–15, which published in the **Federal Register** on July 12, 2004 (69 FR 41754), and was codified in 27 CFR 9.169. The viticultural area lies to the southeast of the proposed Big Valley District—Lake County viticultural area and due east of the proposed Kelsey Bench—Lake County viticultural area.

When the Red Hills Lake County viticultural area was established, part of its western boundary was determined using a 1959 version of the Kelseyville Quadrangle USGS map with a 1975 photorevision date. A portion of the western boundary follows an unnamed, unimproved road from the intersection of Bottle Rock Road and Coal Creek Road to State Highway 29/175. The boundary then continues across the highway to a second unnamed, unimproved road, and then continues along that road in a northwesterly direction to the intersection with a third unnamed, unimproved road running east-west just north of the common boundary line between sections 24 and 25 on the map. The written boundary description of the viticultural area appears in § 9.169(c) of the current regulations, and paragraphs (c)(15) and (c)(16) refer to the three unnamed, unimproved roads.

The petition to establish the proposed Kelsey Bench—Lake County viticultural area uses the 1993 version of the Kelseyville Quadrangle USGS map, which is the most recent version of the map. According to the petitioner, the intent was to have the eastern boundary of the proposed Kelsey Bench—Lake County viticultural area abut the western boundary of the Red Hills Lake County viticultural area. However, the two unnamed, unimproved roads that appear north of State Highway 29/175 on the 1959 version of the map mentioned above do not appear on the 1993 version, making it difficult to ensure that the two boundaries actually touch and do not either overlap or leave a gap. After discussions with TTB, the petitioner decided to request a modification of the Red Hills Lake County viticultural area boundary using features that appear on the 1993 version of the Kelseyville Quadrangle map. TTB agrees that aligning the two boundaries by modifying the Red Hills Lake County viticultural area boundary to use features found on the latest version of the map would be more practical and accurate than determining the boundary of the proposed Kelsey Bench—Lake County viticultural area using the outdated 1959 map.

The proposed boundary line between the existing and proposed viticultural areas follows the original Red Hills Lake County viticultural area boundary as closely as possible using features identifiable on the 1993 map. The proposed modification would result in the addition of approximately 7 acres to the Red Hills Lake County viticultural area. According to the petitioner, there are currently no growers in the small region that would be affected by the proposed boundary change. The petitioner also provided TTB with a letter from a representative of the Red Hills Lake County growers committee and from a grower whose vineyard is within the Red Hills Lake County viticultural area near the region of the proposed boundary modification. Both letters express support for the proposed boundary modification.

The proposed boundary change would affect the western portion of the boundary of the Red Hills Lake County viticultural area that appears on the Kelseyville Quadrangle map. The proposed boundary modification continues to follow the unimproved road that runs northeast from the intersection of Cole Creek Road and Bottle Rock Road to State Highway 29/175, which still appears on the 1993 map. From that point, however, the proposed boundary then proceeds east along the highway to the 1,720-foot elevation contour line, just west of the marked 1,758 benchmark. The proposed boundary then proceeds northwest along the 1,720-foot elevation contour line to the common boundary line between sections 23 and 24 on the map, and then proceeds north along the common boundary line to Wilkerson Road. From that point, the written description of the Red Hills Lake County viticultural area boundary remains unchanged.

TTB Determination

TTB concludes that the petitions to establish the 11,000-acre Big Valley District—Lake County and the 9,100-acre Kelsey Bench—Lake County viticultural areas and modify the boundary of the established Red Hills Lake County viticultural area merit consideration and public comment, as invited in this notice.

Boundary Description

See the narrative boundary description of the petitioned-for viticultural areas and proposed boundary modification in the proposed regulatory text published at the end of this notice.

Maps

The petitioner provided the required maps, and they are listed below in the proposed regulatory text.

Impact on Current Wine Labels

Part 4 of the TTB regulations prohibits any reference on a wine label that indicates or implies an origin other than the wine's true place of origin. If TTB establishes these proposed viticultural area, their names, ''Big Valley District—Lake County'' and ''Kelsey Bench—Lake County,'' will both be recognized as terms of viticultural significance under 27 CFR 4.39(i)(3). TTB believes that the term ''Kelsey Bench'' also has viticultural significance, as this name appears to apply only to this particular region of Lake County, California, and use of the name could imply that a wine originated within the proposed viticultural area. Additionally, according to both the petition and an Internet search conducted by TTB, the term ''Kelseyville Bench'' is used synonymously with ''Kelsey Bench'' to describe the region within the proposed ''Kelsey Bench—Lake County'' viticultural area. Therefore, TTB believes the term ''Kelseyville Bench'' also has viticultural significance. If this proposed regulatory text is adopted as a final rule, wine bottlers using ''Big Valley District—Lake County,'' ''Kelsey Bench—Lake County,'' ''Kelsey Bench,'' or ''Kelseyville Bench'' in a brand name, including a trademark, or in another label reference as to the origin of the wine, would have to ensure that the product is eligible to use the appropriate viticultural area's full name as an appellation of origin. The text of the proposed regulation clarifies this point.

On the other hand, TTB does not believe that the terms ''Big Valley,'' ''Kelseyville,'' or ''Lake County,'' standing alone, would have viticultural significance in relation to this proposed viticultural area. The GNIS Web site shows the name ''Big Valley'' used in reference to 98 locations, including populated places in 13 states, so TTB believes that ''Big Valley,'' standing alone, would not necessarily imply that a wine originated within the proposed viticultural area. Although the results of a GNIS search for the term ''Kelseyville'' all relate to the town of Kelseyville in Lake County, California, the town, itself, is divided between the proposed Big Valley District—Lake County and Kelsey Bench—Lake County viticultural areas. Therefore, because the term is not identified with only one of the proposed viticultural areas, TTB does not believe that ''Kelseyville,'' standing alone, has viticultural significance. Additionally, ''Lake County,'' standing alone, is already a term of viticultural significance as a county appellation of origin under 27 CFR 4.25(a)(1)(iv), and under 27 CFR 4.39(i)(3), which states that a term has viticultural significance when it is the name of a county. Therefore, the part 9 regulatory text set forth in this proposed rule specifies only ''Big Valley District—Lake County,'' ''Kelsey Bench—Lake County,'' ''Kelsey Bench,'' and ''Kelseyville Bench'' as terms of viticultural significance for purposes of part 4 of the TTB regulations.

The approval of the proposed Big Valley District–Lake County and Kelsey Bench–Lake County viticultural areas would not affect any existing viticultural area, and any bottlers using ''Clear Lake'' or ''North Coast'' on their labels as an appellation of origin or in a brand name for wines made from grapes grown within the Clear Lake or North Coast viticultural areas would not be affected by the establishment of these new viticultural areas. The establishment of the Big Valley District–Lake County viticultural area would allow vintners to use ''Big Valley District–Lake County,'' ''Clear Lake,'' and ''North Coast'' as appellations of origin for wines made from grapes grown within the Big Valley District–Lake County viticultural area, if the wines meet the eligibility requirements for the appellation. The establishment of the Kelsey Bench–Lake County viticultural area would allow vintners to use ''Kelsey Bench–Lake County,'' ''Clear Lake,'' and ''North Coast'' as appellations of origin for wines made from grapes grown within the Kelsey Bench–Lake County viticultural area if the wines meet the eligibility requirements for the appellation.

For a wine to be labeled with a viticultural area name or with a brand name that includes a viticultural area name or other term identified as being viticulturally significant in part 9 of the TTB regulations, at least 85 percent of the wine must be derived from grapes grown within the area represented by that name or other term, and the wine must meet the other conditions listed in 27 CFR 4.25(e)(3). If the wine is not eligible for labeling with the viticultural area name or other viticulturally significant term and that name or term appears in the brand name, then the label is not in compliance and the bottler must change the brand name and obtain approval of a new label. Similarly, if the viticultural area name or other viticulturally significant term appears in another reference on the label in a misleading manner, the bottler would have to obtain approval of a new label.

Different rules apply if a wine has a brand name containing a viticultural area name or other viticulturally significant term that was used as a brand name on a label approved before July 7, 1986. See 27 CFR 4.39(i)(2) for details.

Public Participation

Comments Invited

TTB invites comments from interested members of the public on whether the Bureau should establish the proposed Big Valley District–Lake County viticultural area, and on whether the Bureau should establish the proposed Kelsey Bench–Lake County viticultural area. TTB is interested in receiving comments on the sufficiency and accuracy of the name, boundary, climate, soil, and other required information submitted as part of the petitions in support of the establishment of the two proposed viticultural areas. Please provide any available specific information in support of your comment. In addition, given the proposed Big Valley District–Lake County and Kelsey Bench–Lake County viticultural areas' location within both the existing Clear Lake and North Coast viticultural areas, TTB is interested in comments on whether the evidence submitted in the petitions regarding the distinguishing features of the proposed viticultural areas sufficiently differentiates them from the existing Clear Lake and North Coast viticultural areas. TTB is also interested in comments on whether the geographic features of either or both of the proposed viticultural areas are so distinguishable from the Clear Lake and North Coast viticultural areas that either or both of the proposed Big Valley District–Lake County and Kelsey Bench–Lake County viticultural areas should no longer be part of those viticultural areas. Finally, TTB is

interested in comments regarding the proposed boundary modification of the established Red Hills Lake County viticultural area. Please provide any available specific information in support of your comments.

Because of the potential impact of the establishment of the proposed Big Valley District–Lake County and Kelsey Bench–Lake County viticultural areas on wine labels that include the terms ''Big Valley District–Lake County,'' ''Kelsey Bench–Lake County,'' ''Kelsey Bench,'' or ''Kelseyville Bench'' as discussed above under Impact on Current Wine Labels, TTB is also inviting comments regarding whether there will be a conflict between the proposed area names and recognized terms of viticultural significance and any brand names currently appearing on existing wine labels. If a commenter believes that a conflict will arise, the comment should describe the nature of that conflict, including any anticipated negative economic impact that approval of the proposed viticultural area will have on an existing viticultural enterprise. TTB is also interested in receiving suggestions for ways to avoid conflicts, for example, by adopting modified or different names for the proposed viticultural areas.

Submitting Comments

You may submit comments on this notice by using one of the following three methods:

- *Federal e-Rulemaking Portal:* You may send comments via the online comment form posted with this notice within Docket No. TTB–2013–0003 on ''Regulations.gov,'' the Federal e-rulemaking portal, at *http://www.regulations.gov.* A direct link to that docket is available under Notice No. 134 on the TTB Web site at *http://www.ttb.gov/wine/wine-rulemaking.shtml.* Supplemental files may be attached to comments submitted via Regulations.gov. For complete instructions on how to use Regulations.gov, visit the site and click on the ''Help'' tab.
- *U.S. Mail:* You may send comments via postal mail to the Director, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Box 12, Washington, DC 20005.
- *Hand Delivery/Courier:* You may hand-carry your comments or have them hand-carried to the Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Suite 200–E, Washington, DC 20005.

Please submit your comments by the closing date shown above in this notice. Your comments must reference Notice No. 134 and include your name and mailing address. Your comments also must be made in English, be legible, and be written in language acceptable for public disclosure. TTB does not acknowledge receipt of comments, and considers all comments as originals.

In your comment, please state if you are commenting on your own behalf or behalf of an association, business, or other entity. If you are commenting on behalf of an entity, your comment must include the entity's name as well as your name and position title. If you comment via *http://www.regulations.gov,* please enter the entity's name in the ''Organization'' blank of the online comment form. If you comment via postal mail or hand delivery/courier, please submit your entity's comment on letterhead.

You may also write to the Administrator before the comment closing date to ask for a public hearing. The Administrator reserves the right to determine whether to hold a public hearing.

Confidentiality

All submitted comments and attachments are part of the public record and subject to disclosure. Do not include, attach, or enclose any material in or with your comments that you consider to be confidential or inappropriate for public disclosure.

Public Disclosure

On the Federal e-rulemaking portal, Regulations.gov, TTB will post, and you may view, copies of this notice, selected supporting materials, and any online or mailed comments TTB receives about this. A direct link to the *Regulations.gov* docket containing this notice and the posted comments received on it is available on the TTB Web site at *http://www.ttb.gov/wine/wine-rulemaking.shtml* under Notice No. 134. You may also reach the docket containing this notice and the posted comments received on it through the *Regulations.gov* search page at *http://www.regulations.gov.* For instructions on how to use *Regulations.gov*, visit the site and click on the ''Help'' tab.

All posted comments will display the commenter's name, organization (if any), city, and State, and, in the case of mailed comments, all address information, including email addresses. TTB may omit voluminous attachments or material that TTB considers unsuitable for posting.

You may view copies of this notice, all related petitions, maps and other supporting materials, and any electronic or mailed comments TTB receives about this proposal by appointment at the TTB Information Resource Center, 1310 G Street NW., Washington, DC 20220. You may also obtain copies at 20 cents per 8.5- x 11-inch page. Contact the information specialist at the above address or by telephone at 202–453–2270 to schedule an appointment or to request copies of comments or other materials.

Regulatory Flexibility Act

TTB certifies that this proposed regulation, if adopted, would not have a significant economic impact on a substantial number of small entities. The proposed regulation imposes no new reporting, recordkeeping, or other administrative requirement. Any benefit derived from the use of a viticultural area name would be the result of a proprietor's efforts and consumer acceptance of wines from that area. Therefore, no regulatory flexibility analysis is required.

Executive Order 12866

This proposed rule is not a significant regulatory action as defined by Executive Order 12866. Therefore, it requires no regulatory assessment.

Drafting Information

Karen A. Thornton of the Regulations and Rulings Division drafted this proposed rule.

List of Subjects in 27 CFR Part 9

Wine.

Proposed Regulatory Amendment

For the reasons discussed in the preamble, TTB proposes to amend title 27, chapter I, part 9, Code of Federal Regulations, as follows:

PART 9—AMERICAN VITICULTURAL AREAS

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

Authority: 27 U.S.C. 205.

Subpart C—Approved American Viticultural Areas

■ 2. Amend § 9.169 by revising paragraphs (b)(4), (c)(15), (c)(16), and (c)(17) to read as follows:

§ 9.169 Red Hills Lake County.

* * * * *

(b) * * *

(4) Kelseyville Quadrangle—California. 1993.

(c) * * *

(15) Proceed east and then northeast approximately 0.4 miles along the unimproved road to the road's intersection with State Highway 29/175, then proceed east along State Highway

29/175 to the intersection of the highway with the 1,720-foot elevation line located just west of the 1,758-foot benchmark (BM) in section 25, T13N, R9W (Kelseyville Quadrangle); then

(16) Proceed northwest along the 1,720-foot elevation line to the common boundary line between sections 25 and 26, T13N, R9W; then

(17) Proceed north along the common boundary line between sections 25 and 26, T13N, R9W, and then the common boundary line between sections 23 and 24, T13N, R9W, (partially concurrent with Wilkinson Road) to the intersection of the common section 23–24 boundary line with the 1,600-foot elevation line (Kelseyville Quadrangle); then

* * * * *

■ 3. Subpart C is amended by adding § 9._____ to read as follows:

§ 9.____ Big Valley District–Lake County.

(a) *Name.* The name of the viticultural area described in this section is ''Big Valley District–Lake County''. For purposes of part 4 of this chapter, ''Big Valley District–Lake County'' is a term of viticultural significance.

(b) *Approved maps.* The four United States Geological Survey (USGS) 1:24,000 scale topographic maps used to determine the boundary of the Big Valley District–Lake County viticultural area are titled:

(1) Lucerne, CA 1996;

(2) Kelseyville, Calif., 1993;

(3) Highland Springs, Calif., 1993; and

(4) Lakeport. Calif., 1958; photorevised 1978; minor revision 1994.

(c) *Boundary.* The Big Valley District–Lake County viticultural area is located in Lake County, California. The boundary of the Big Valley District–Lake County viticultural area is as described below:

(1) The beginning point is on the Lucerne map at the point where Cole Creek flows into Clear Lake, section 36, T14N/R9W. From the beginning point, proceed southerly (upstream) along Cole Creek approximately 0.9 mile to the creek's intersection with Soda Bay Road, section 1, T13N/R9W; then

(2) Proceed east on Soda Bay Road less than 0.1 mile to the road's intersection with the unnamed light-duty road known locally as Clark Drive, section 1, T13N/R09W; then

(3) Proceed southeast in a straight line less than 0.1 mile to the 1,400-foot elevation line, section 1, T13N/R9W; then

(4) Proceed southerly along the 1,400-foot elevation line, crossing onto the Kelseyville map, to the line's intersection with a marked cemetery east of Kelseyville (in the northeast quadrant of section 14, T13N/R9W), and then continue along the 1,400-foot elevation line approximately 0.35 mile to the line's intersection with an unnamed, unimproved road which runs north from Konocti Road, section 13, T13N/R9W; then

(5) Proceed south-southeast along the unnamed, unimproved road to the road's intersection with the improved portion of Konocti Road, section 13, T13N/R9W; then

(6) Proceed west on Konocti Road approximately 0.9 mile to the road's intersection with an unnamed light-duty road within Kelseyville known locally as Main Street, section 14, T13N/R9W; then

(7) Proceed south-southeast on Main Street approximately 0.35 mile to its intersection with State Highway 29/175, section 14, T13N/R9W; then

(8) Proceed west-northwest on State Highway 29/175 approximately 0.4 mile to the highway's intersection with Kelsey Creek, section 14, T13N/R9W; then

(9) Proceed northwesterly (downstream) along Kelsey Creek approximately 0.5 mile to the creek's intersection with an unnamed light-duty road known locally as Big Valley Road (or North Main Street), section 15, T13N/R9W; then

(10) Proceed west and then northwest on Big Valley Road approximately 0.35 mile to the road's intersection with Merritt Road, southern boundary of section 10, T13N/R9W; then

(11) Proceed west on Merritt Road approximately 0.3 mile to the road's intersection with the 1,400-foot elevation line, southern boundary of section 10, T13N/R9W; then

(12) Proceed northwesterly along the 1,400-foot elevation line to the line's intersection with State Highway 29/175, section 9, T13N/R9W, and then continue southerly along the 1,400-foot elevation to the line's intersection with Merritt Road, southern boundary of section 9, T13N/R9W; then

(13) Proceed west on Merritt Road approximately 0.1 mile to the road's intersection with Hill Creek, southern boundary of section 9, T13N/R9W; then

(14) Proceed southerly (upstream) along Hill Creek approximately 0.9 mile to the creek's intersection with Bell Hill Road, section 16, T13N/R9W; then

(15) Proceed west then southwest on Bell Hill Road approximately 0.15 mile, passing the intersection of Bell Hill Road and Hummel Lane, to Bell Hill Road's intersection with the 1,400-foot elevation line, section 16, T13N/R9W; then

(16) Proceed westerly and then southwesterly along the meandering 1,400-foot elevation line, crossing onto the Highland Springs map, to the line's first intersection with Bell Hill Road in section 20, T13N/R9W; then

(17) Proceed west on the meandering Bell Hill Road, crossing Adobe Creek, to the road's intersection with Highland Springs Road, section 30, T13N/R9W; then

(18) Proceed north on Highland Springs Road approximately 2.8 miles to the road's intersection with Mathews Road at the northwest corner of section 8, T13N/R9W; then

(19) Proceed west on Mathews Road approximately 0.7 mile to the road's intersection with an unnamed paved road known locally as Ackley Road, southern boundary of section 6, T13N/R9W; then

(20) Proceed north on Ackley Road approximately 0.9 mile, crossing onto the Lakeport map, to the road's intersection with State Highway 29/175, section 6; T13N/R9W; then

(21) Proceed due north-northeast in a straight line approximately 0.15 mile to the unnamed secondary highway known locally as Soda Bay Road, northern boundary of section 6, T13N/R9W; then

(22) Proceed east on Soda Bay Road approximately 0.35 mile to the road's intersection with Manning Creek, northern boundary of section 6, T13N/R9W; then

(23) Proceed northwesterly (downstream) along Manning Creek to the shore of Clear Lake, section 30, T14N/R9W; then

(24) Proceed easterly along the meandering shore of Clear Lake, crossing onto the Lucerne map, to the beginning point.

■ 4. Subpart C is amended by adding § 9._____ to read as follows:

§ 9.____ Kelsey Bench–Lake County.

(a) *Name.* The name of the viticultural area described in this section is ''Kelsey Bench–Lake County.'' For purposes of part 4 of this chapter, ''Kelsey Bench–Lake County'', ''Kelsey Bench'', and ''Kelseyville Bench'' are terms of viticultural significance.

(b) *Approved maps.* The two United States Geological Survey (USGS) 1:24,000 scale topographic maps used to determine the boundary of the Kelsey Bench–Lake County viticultural area are titled:

(1) Kelseyville, Calif., 1993; and

(2) Highland Springs, Calif., 1993.

(c) *Boundary.* The Kelsey Bench–Lake County viticultural area is located in Lake County, California. The boundary of the Kelsey Bench–Lake County viticultural area is described below:

(1) The beginning point is on the Kelseyville map within the town of

Kelseyville at the intersection of Konocti Road and Main Street (not named on the map), section 14, T13N/R9W. From the beginning point, proceed east on Konocti Road approximately 0.9 mile to the road's 3-way intersection with an unnamed, unimproved road to the south, section 13, T13N/R9W; then

(2) Proceed south on the unnamed, unimproved road approximately 0.35 mile to a fork in the road, and continue on the eastern branch of the fork approximately 0.4 mile to the point where the road intersects a straight line drawn westward from the marked 2,493 elevation point in section 19, T13N/R9W, to the intersection of the 1,600-foot elevation line and the eastern boundary of section 23, T13N/R9W (which is concurrent with Wilkerson Road); then

(3) Proceed westerly along the straight line described in paragraph (c)(2) approximately 0.3 mile to the line's western end at the intersection of the 1,600-foot elevation line and the eastern boundary of section 23, T13N/R9W; then

(4) Proceed south along the eastern boundaries of sections 23 and 26, T13N/R9W, approximately 0.8 mile to the first intersection of the eastern boundary of section 26 and the 1,720-foot elevation line; then

(5) Proceed southeasterly along the 1,720-foot elevation line to the line's intersection with State Highway 29/175, just west of BM 1758, section 25, T13N/R9W; then

(6) Proceed west on State Highway 29/175 approximately 0.15 mile to the highway's intersection with an unnamed, unimproved road, section 25, T13N/R9W; then

(7) Proceed southwest then west on the unnamed, unimproved road approximately 0.4 mile to the road's intersection with Cole Creek Road at Bottle Rock Road, section 25, T13N/R9W; then

(8) Proceed west on Cole Creek Road approximately 0.65 mile to the road's intersection with an unnamed light-duty road known locally as Live Oak Drive (at BM 1625), section 26, T13N/R9W; then

(9) Proceed northwest on Live Oak Drive to the road's intersection with Gross Road (at BM 1423), section 26, T13N/R9W; then

(10) Proceed south on Gross Road approximately 0.65 mile to the road's intersection with the 1,600-foot elevation line, section 26, T13N/R9W; then

(11) Proceed southerly along the meandering 1,600-foot elevation line to the line's intersection with Sweetwater Creek section 10, T12N/R9W; then

(12) Proceed due west in a straight line approximately 0.6 mile to the line's first intersection with the 1,600-foot elevation after crossing Kelsey Creek, section 10, T12N/R9W; then

(13) Proceed westerly and then northerly along the meandering 1,600-foot elevation line to the line's intersection with Kelsey Creek Drive, section 4, T12N/R9W; then

(14) Proceed west on Kelsey Creek Drive and then Adobe Creek Drive, crossing onto the Highland Springs map, and continue north-northwest on Adobe Creek Drive, a total distance of approximately 3.25 miles, to the marked 1,439-foot elevation point in section 29, T13N/R9W; then

(15) Proceed west-southwest in a straight line that passes through the marked 1,559-foot elevation point in section 29, T13N/R9W, and continue in the same direction to the line's intersection with an unnamed, light-duty road known locally as East Highland Springs Road, a total distance of approximately 0.6 mile, section 30, T13N, R9W; then

(16) Proceed north on East Highland Springs Road approximately 0.5 mile, to the road's intersection with an unnamed road in the northeast quadrant of section 30, T13N/R9W; then

(17) Proceed northwest on the unnamed road to the road's end point, then continue due north-northwest in a straight line, a total distance of approximately 0.3 mile, to the line's intersection with the southern boundary of section 19, T13N/R9W; then

(18) Proceed west along the southern boundary of section 19, T13N/R9W, approximately 0.5 mile to the section's southwest corner; then

(19) Proceed north along the western boundary of section 19, T13N/R9W, approximately 0.3 mile to the section line's seventh intersection with the 1,600-foot elevation line; then

(20) Proceed westerly, northwesterly, and then easterly along the meandering 1,600-foot elevation line to the line's second intersection with the northern boundary of section 19, T13N/R9w; then

(21) Proceed east along the northern boundary of section 19, T13N/R9W, approximately 0.35 mile to the section boundary's intersection with an unnamed road known locally as Fritch Road; then

(22) Proceed east on Fritch Road approximately 0.4 miles to the road's intersection with Highland Springs Road, section 18, T13N/R9W; then

(23) Proceed south on Highland Springs Road approximately 0.8 mile to the road's intersection with Bell Hill Road, section 19, T13N/R9W; then

(24) Proceed eastward on the meandering Bell Hill Road approximately 1.4 miles to the road's last intersection with the 1,400-foot elevation line in section 20, T13N/R9W; then

(25) Proceed northeasterly along the 1,400-foot elevation line, crossing onto the Kelseyville map, to the line's first intersection with Bell Hill Road in the southeast quadrant of section 16, T13N/R9W; then

(26) Proceed northeast and then east on Bell Hill Road approximately 0.15 mile to the road's intersection with Hill Creek, section 16, T13N/R9W; then

(27) Proceed northerly (downstream) along Hill Creek approximately 0.9 mile to the creek's intersection with Merritt Road, section 16, T13N/R9W; then

(28) Proceed east on Merritt Road approximately 0.1 mile to the road's intersection with the 1,400-foot elevation line, northern boundary of section 16, T13N/R9W; then

(29) Proceed northerly along the 1,400-foot elevation line approximately 0.2 mile to State Highway 29/175, section 9, T13N/R9W, and then continue northerly and then southeasterly along the 1,400-foot elevation line approximately 0.5 mile to the line's intersection with Merritt Road, northern boundary of section 15, T13N/R9W; then

(30) Proceed east on Merritt Road approximately 0.3 mile to the road's intersection with an unnamed road known locally as Big Valley Road (or North Main Street), northern boundary of section 15, T13N/R9W; then

(31) Proceed south then east on Big Valley Road (North Main Street) approximately 0.35 mile to the road's intersection with Kelsey Creek, section 15, T13N/R9W; then

(32) Proceed southerly (upstream) along Kelsey Creek approximately 0.5 mile to the creek's intersection with State Highway 29/175, section 14, T13N/R9W; then

(33) Proceed southeast on State Highway 29/175 approximately 0.4 mile, crossing Live Oak Drive, to the highway's intersection with an unnamed road known locally as Main Street, section 14, T13N/R9W; then

(34) Proceed north on Main Street approximately 0.3 mile, returning to the beginning point.

Signed: March 28, 2013.

John J. Manfreda,

Administrator.

[FR Doc. 2013–07882 Filed 4–4–13; 8:45 am]

BILLING CODE 4810–31–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR 101,104,105,106

[Docket No. USCG–2007–28915]

Transportation Worker Identification Credential (TWIC)—Reader Requirements

AGENCY: Coast Guard, DHS.

ACTION: Notice of public meeting on proposed rulemaking; request for comments.

SUMMARY: The Coast Guard announces a public meeting to take place on May 2, 2013, in Seattle, Washington to receive comments on a notice of proposed rulemaking published in the **Federal Register** on March 22, 2013, under the title ''Transportation Worker Identification Credential (TWIC)—Reader Requirements.'' The Coast Guard encourages members of the public to attend this meeting and provide oral comments on the notice of proposed rulemaking on TWIC reader requirements.

DATES: A public meeting will be held on Thursday, May 2, 2013, from 1:00 p.m. to 5:00 p.m. to provide an opportunity for oral comments. Coast Guard personnel will accept written comments and related materials at the public meeting as well. Written comments may also be submitted in response to the notice of proposed rulemaking referenced in the **SUPPLEMENTARY INFORMATION** section. The comment period for the notice of proposed rulemaking will close on May 21, 2013. All written comments and related materials submitted before or after the meeting must either be submitted to our online docket via *http://www.regulations.gov* on or before May 21, 2013, or reach the Docket Management Facility by that date.

ADDRESSES: The public meeting will be held at the Seattle Airport Marriott, 3201 South 176th Street, Seattle, Washington 98188. The building is accessible by taxi, public transit, and privately-owned conveyance.

This meeting is open to the public. Please note that the session may adjourn early if all business, concerns, and questions are addressed. You may submit written comments identified by docket number USCG–2007–28915 before or after the meeting using any one of the following methods:

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

(2) *Fax:* 202–493–2251.

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

(4) *Hand delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

To avoid duplication, please use only one of these four methods. Our online docket for this notice is available on the Internet at *http://www.regulations.gov* under docket number USCG–2007–28915.

FOR FURTHER INFORMATION CONTACT: If you have questions concerning the meeting, please call or email LCDR Gregory Callaghan, Commandant (CG–FAC–2), Coast Guard; telephone 202–372–1168, email *Gregory.A.Callaghan@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Ms. Barbara Hairston, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Background and Purpose

On March 22, 2013, the Coast Guard published a notice of proposed rulemaking (NPRM) in the **Federal Register** (78 FR 17781), in which we proposed to require owners and operators of certain vessels and facilities regulated by the Coast Guard to use electronic readers designed to work with the Transportation Worker Identification Credential (TWIC) as an access control measure. The NPRM also proposed additional requirements associated with electronic TWIC readers, including recordkeeping requirements for those owners and operators required to use an electronic TWIC reader, and security plan amendments to incorporate TWIC reader requirements. The TWIC program, including the TWIC reader requirements proposed in the NPRM, is an important component of the Coast Guard's multi-layered system of access control requirements and other measures designed to enhance maritime security.

As authorized by the Maritime Transportation Security Act of 2002 [1] (MTSA), the Transportation Security Administration (TSA) established the TWIC program to address identity management shortcomings and vulnerabilities identified in the nation's transportation system and to comply with the MTSA statutory requirements. On January 25, 2007, the Department of Homeland Security (DHS), through the Coast Guard and TSA, promulgated regulations that require mariners and other individuals granted unescorted access to secure areas of MTSA-regulated vessels or facilities to undergo a security threat assessment by TSA and obtain a TWIC.[2]

This NPRM that is the subject of this public meeting, which would require owners and operators of certain types of vessels and facilities to use electronic TWIC readers, would advance the goals of the TWIC program. In crafting the proposals in the NPRM, the Coast Guard conducted a risk-based analysis of MTSA-regulated vessels and facilities to categorize them into one of three risk groups, labeled A, B, and C. Risk Group A is comprised of vessels and facilities that present the highest risk of being involved in a transportation security incident (TSI).[3] The NPRM proposes TWIC reader requirements for vessels and facilities in Risk Group A. Under the NPRM, vessels and facilities in Risk Groups B and C present progressively lower risks, and would continue to follow existing regulatory requirements for visual TWIC inspection.

The Coast Guard believes that in addition to receiving written comments on the NPRM, a public meeting would benefit the impacted community by providing another forum to raise relevant issues. Also, the Security and Accountability For Every (SAFE) Port Act of 2006 [4] requires the Coast Guard to hold at least one public hearing before promulgating final TWIC reader regulations (*see* 46 U.S.C. 70105(k)(3)). This public meeting will further enable the Coast Guard to craft policy informed by the public.

We may hold one or more additional public meetings regarding the proposals in the NPRM on TWIC reader requirements. We will notify the public of the date(s), time(s), location(s), and other details of any such meeting(s) by publishing a separate notice in the **Federal Register** as soon as we have information available.

You may view the NPRM, written comments, and supporting documents in the online docket by going to

[1] Public Law 107–295, 116 Stat. 2064 (Nov. 2, 2002).

[2] Transportation Worker Identification Credential (TWIC) Implementation in the Maritime Sector; Hazardous Materials Endorsement for a Commercial Driver's License, 72 FR 3492 (Jan. 25, 2007).

[3] A transportation security incident is a security incident resulting in a significant loss of life, environmental damage, transportation system disruption, or economic disruption in a particular area, as defined in 46 U.S.C. 70101 (49 CFR 1572.103).

[4] Public Law 109–347, 120 Stat. 1884 (Oct. 13, 2006).

http://www.regulations.gov and using ''USCG–2007–28915'' as your search term. Locate the NPRM among the search results and use the filters on the left side of the page to search for specific types of documents. If you do not have access to the Internet, you may view the docket by visiting the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. The Coast Guard has an agreement with the Department of Transportation to use its Docket Management Facility.

We encourage you to participate by submitting comments either orally at the meeting or in writing. If you bring written comments to the meeting, you may submit them to Coast Guard personnel specified at the meeting to receive written comments. These comments will be submitted to our online public docket. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided.

Anyone can search the electronic form of comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, or other entity). You may review a Privacy Act notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

Information on Services for Individuals With Disabilities

For information on facilities or services for individuals with disabilities or to request special assistance at the public meeting, contact LCDR Gregory Callaghan at the telephone number or email address indicated under the **FOR FURTHER INFORMATION CONTACT** section of this notice.

Public Meeting

The Coast Guard will hold a public meeting regarding the ''Transportation Worker Identification Credential (TWIC)—Reader Requirements'' NPRM (78 FR 17781) on Thursday, May 2, 2013 from 1:00 p.m. to 5:00 p.m., at the Seattle Airport Marriott, 3201 South 176th Street, Seattle, Washington 98188. The building is accessible by taxi, public transit, and privately-owned conveyance. Please note that the session may adjourn early if all business, concerns, and questions are addressed. We will post a written summary of the meeting and oral comments in the docket.

Authority

This notice is issued under the authority of 46 U.S.C. 70105(k)(3) and 5 U.S.C. 552(a).

Dated: April 1, 2013.

A.E. Tucci,

Captain, U.S. Coast Guard, Chief, Office of Port and Facility Compliance (CG–FAC).

[FR Doc. 2013–07910 Filed 4–4–13; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2013–0026]

RIN 1625–AA00

Safety Zones; Swim Events in the Captain of the Port New York Zone; Hudson River, East River, Upper New York Bay, Lower New York Bay; New York, NY

AGENCY: Coast Guard, DHS.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: The Coast Guard proposes to establish five temporary safety zones for swim events within the Captain of the Port (COTP) New York Zone. These proposed zones will be established on the navigable waters of the Hudson River, East River, Upper New York Bay, and Lower New York Bay. These temporary safety zones are necessary to protect the maritime public and event participants from the hazards associated with these events. Persons and vessels are prohibited from entering into, transiting through, mooring, or anchoring within the safety zones unless authorized by the COTP New York or the designated representative.

DATES: Comments and related material must be received by the Coast Guard on or before June 4, 2013.

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

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

(2) *Fax:* 202–493–2251.

(3) *Mail or Delivery:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001. Deliveries accepted between 9 a.m. and 5 p.m., Monday through Friday, except federal holidays. The telephone number is 202–366–9329.

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

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Junior Grade Kristopher Kesting, Coast Guard; telephone (718)354–4154, email *Kristopher.R.Kesting@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Barbara Hairston, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

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

A. Public Participation and Request for Comments

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

1. Submitting Comments

If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online at *http://www.regulations.gov,* or by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online, it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov,* type the docket number (USCG–2013–0026) in the ''SEARCH'' box and click ''SEARCH.'' Click on ''Submit a

Comment'' on the line associated with this rulemaking.

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 may change the rule based on your comments.

2. Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type the docket number (USCG–2013–0026) in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rulemaking. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

3. Privacy Act

Anyone can search the electronic form of comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

4. Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for one on or before April 12, 2013 using one of the methods specified under **ADDRESSES**. Please explain why you believe a public meeting would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register.**

B. Regulatory History and Information

In previous years, the Coast Guard has established special local regulations, regulated areas, and safety zones on a case-by-case basis to ensure the protection of the maritime public and event participants from hazards associated with these events. The Coast Guard has not received public comments or concerns regarding the impact to waterway traffic from these events.

C. Basis and Purpose

The legal basis for the proposed rule is 33 U.S.C. 1266, 1231, 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Public Law 107–295, 116 Stat. 2064; and Department of Homeland Security Delegation No. 0170.1, which collectively authorize the Coast Guard to define regulatory safety zones.

Marine events are frequently held on the navigable waters within the COTP Sector New York Zone. The COTP has determined that swimming events in close proximity to marine traffic pose significant risk to public safety and property. The combination of increased numbers of recreation vessels, congested waterways, and large numbers of swimmers in the water has the potential to result in serious injuries or fatalities. In order to protect the safety of all waterway users including event participants and spectators, this temporary rule establishes temporary safety zones for the duration of the events.

This rule prevents vessels from entering into, transiting through, and mooring or anchoring within the areas specifically designated as the regulated areas during the periods of enforcement unless authorized by the COTP, or the designated representative.

D. Discussion of Proposed Rule

This temporary rule creates safety zones for five swim events on the navigable waters of the Hudson River, East River, Upper New York Bay and Lower New York Bay. A portion of the navigable waters will be closed during the effective periods to all vessel traffic except local, state or Coast Guard patrol crafts. The events and locations are as follows:

(1) Hudson Valley Triathlon: Waters of the Hudson River in the vicinity of Ulster Landing, NY.

(2) Coney Island to New Dorp Beach Swim: Waters of the Lower New York Bay spanning from Rockaway Point, Coney Island to New Dorp Beach, Staten Island.

(3) Brooklyn Bridge Swim: Waters of the East River in the vicinity of Brooklyn Bridge Park, Brooklyn, NY and East River Park, New York, NY.

(4) The Liberty to Freedom Swim: Waters of the Upper New York Bay, from Liberty Island, NJ to North Cove, New York, NY.

(5) Ederle Swim: Waters of the Hudson River between North Cove Marina, New York, NY and Sandy Hook, NJ.

The proposed regulation would prevent vessels from transiting in close proximity to swimmers in areas designated as safety zones during the periods of enforcement to ensure protection of the maritime public and event participants from hazards associated with the listed swim events.

Event sponsors, designated participants, and official patrol vessels will be allowed to enter the regulated areas. Spectators and other vessels not registered as event participants will not be permitted to enter the safety zones without permission of the COTP or the designated representative. Marine traffic will be permitted to pass through safety zones at a safe distance from event participants with permission of the COTP or the designated representative.

E. Regulatory Analyses

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

1. Regulatory Planning and Review

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

These safety zones will be of limited duration, and vessels may transit in portions of the affected waterway. Furthermore, vessels may be authorized to transit these zones with the permission of the COTP New York or the designated representative.

Notifications will be made to the local maritime community through the Local Notice to Mariners and Broadcast Notice to Mariners well in advance of the events. No new or additional restrictions would be imposed on vessel traffic.

2. Impact on Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered the impact of this proposed rule on small entities. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule will not have a significant economic impact on a substantial number of small entities.

This rule will affect the following entities, some of which may be small

entities: The owners and operators of vessels intending to transit, fish or anchor in the designated safety zones during the enforcement period of the swim events.

The safety zones will not have significant economic impact on a substantial number of small entities for the following reasons: Vessels will only be restricted from safety zone areas for a short duration of time; vessels may transit in portions of the affected waterway at a safe distance from event participants with permission of the COTP or the designated representative; the Coast Guard has promulgated safety zones in accordance with 33 CFR part 165 for all event areas in the past and has not received notice of any negative impact caused by any of the safety zones; and notifications will be made to the local maritime community through the Local Notice to Mariners and Broadcast Notice to Mariners well in advance of the events.

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

3. Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT**, above. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

4. Collection of Information

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

5. Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this proposed rule under that Order and determined that this rule does not have implications for federalism.

6. Protest Activities

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

7. Unfunded Mandates Reform Act

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

8. Taking of Private Property

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

9. Civil Justice Reform

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

10. Protection of Children From Environmental Health Risks

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

11. Indian Tribal Governments

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

12. Energy Effects

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

13. Technical Standards

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

14. Environment

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 33 U.S.C. 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1 6.04–1, 6.04–6, 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1, which authorizes the Coast Guard to define Safety Zone Regulations.

■ 2. Add § 165.T01–0026 to read as follows:

§ 165.T01–0026 Swim Events in the Captain of the Port New York Zone, Hudson River, East River, Upper New York Bay, Lower New York Bay, New York, NY.

(a) *Regulation.* The general regulations contained in 33 CFR 165.23 as well as the following regulations apply to the swim events listed in the TABLE to 165.T01–0026. These regulations will be enforced for the duration of each swim event. Notifications of exact dates and times of the enforcement period will be made to the local maritime community in the final rule. First Coast Guard District Local Notice to Mariners can be found at *http://www.navcen.uscg.gov/.*

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

(1) Designated Representative. A designated representative is any Coast Guard commissioned, warrant or petty officer of the U.S. Coast Guard who has been designated by the Captain of the Port (COTP) New York Zone to act on his or her behalf.

(2) Official Patrol Vessels. Official patrol vessels may consist of any Coast Guard, Coast Guard Auxiliary, state, or local law enforcement vessels assigned or approved by the COTP. The designated representative may be on an official patrol vessel or may be on shore and will communicate with vessels via VHF–FM radio or loudhailer. In addition, members of the Coast Guard Auxiliary may be present to inform vessel operators of this regulation.

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

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

(d) Spectators or other vessels shall not anchor, block, loiter within, or impede the transit of event participants or official patrol vessels in the regulated areas during the effective dates and times, or dates and times as modified through the Local Notice to Mariners, unless authorized by COTP or the designated representative.

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

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

(g) For all swim events listed in the TABLE to § 165.T01–0026, vessels not associated with the event that are permitted to enter the regulated areas in accordance with section (c), shall maintain a separation of at least 100 yards from the participants.

TABLE 1 TO § 165.T01–0026

1	Hudson River
1.1 Hudson Valley Triathlon	• Date: July 14, 2013. • Location site: All waters of the Hudson River in the vicinity of Ulster Landing, bound by the following points: 42°00′03.7″ N, 073°56′43.1″ W; thence to 41°59′52.5″ N, 073°56′34.2″ W; thence to 42°00′15.1″ N, 073°56′25.2″ W; thence to 42°00′05.4″ N, 073°56′41.9″ W; thence along the shoreline to the point of origin.
2	Lower New York Bay
2.1 Coney Island to New Dorp Beach Swim	• Date: October 14, and 27, 2013. • Location: All waters of the Lower New York Bay spanning from Rockaway Point, Coney Island to New Dorp Beach, Staten Island, bound by the following points: 40°32′33.69″ N, 073°56′25.32″ W; thence to 40°26′50.97″ N, 073°59′01.05″ W; thence to 40°28′52.26″ N, 074°0′21.97″ W; thence to 40°34′13.48″ N, 074°0′07.18″ W; thence back to the point of origin.
3	East River, Upper New York Bay, Lower New York Bay
3.1 Brooklyn Bridge Swim	• Date: July 07, 2013. • Rain Date: NA. • Location: All waters of the East River, bound by the following points: 40°42′17.04″ N, 073°59′21.87″ W; thence to 40°42′12.03″ N, 073°59′46.17″ W; thence to 40°42′24.48″ N, 074°0′4.09″ W; thence to 40°42′34.19 N, 073°59′31.41″ W; thence back to point of origin.
4	Upper New York Bay, Hudson River
4.1 Liberty to Freedom Swim	• Date: September 08, 2013. • Location: All waters of the East River, bound by the following points: 40°42′17.04″ N, 073°59′21.87″ W; thence to 40°42′12.03″ N, 073°59′46.17″ W; thence to 40°42′24.48″ N, 074°0′4.09″ W; thence to 40°42′34.19N, 073°59′31.41″ W; thence back to point of origin.
5	Upper New York Bay, Hudson River [Reserved]
6	Upper New York Bay, Lower New York Bay
6.1 Ederle Swim	• Date: August 18, 19 and 22, 2013.

TABLE 1 TO § 165.T01–0026—Continued

	• Location: All waters of the Hudson River, Upper and Lower New York Bays, bound by the following points: 40°42′48.13″ N, 074°0′58.74″ W; thence to 40°42′3.20″ N, 073°59′54.84″ W; thence to 40°36′32.70″ N, 074°2′10.73″ W; thence to 40°28′4.43 N, 073°59′38.14″ W; thence to 40°28′41.58″ N, 074°0′55.27″ W; thence to 40°38′38.77″ N, 074°4′15.05″ W; thence to 40°43′0.31″ N, 074°1′48.11″ W thence back to point of origin.

Dated: March 2, 2013.

G. Loebl,

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

[FR Doc. 2013–07909 Filed 4–4–13; 8:45 am]

BILLING CODE 9110–04–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

36 CFR Part 1280

RIN 3095–AB77

Use of Meeting Rooms and Public Spaces

AGENCY: National Archives and Records Administration (NARA).

ACTION: Proposed rule.

SUMMARY: NARA proposes to amend its regulations on the public use of NARA facilities in the Washington, DC area. The regulations are being revised to clarify instances where fees may be charged for services related to building use. It also updates contact information for requesting use of NARA public areas in the Washington, DC National Archives Building and the National Archives at College Park.

DATES: Submit comments on or before June 4, 2013.

ADDRESSES: NARA invites interested persons to submit comments on this proposed rule. Please include ''Attn: 3095–AB77'' and your name and mailing address in your comments. Comments may be submitted by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* Submit comments by facsimile transmission to 301–837–0319.
- *Mail:* Send comments to Regulations Comments Desk (SP), Room 4100, Strategy Division, National Archives and Records Administration, 8601 Adelphi Road, College Park, MD 20740–6001.
- *Hand Delivery or Courier:* Deliver comments to 8601 Adelphi Road, College Park, MD.

FOR FURTHER INFORMATION CONTACT: Marilyn Redman at 301–837–3174.

SUPPLEMENTARY INFORMATION: NARA proposes to amend its regulations on the public use of NARA facilities in the Washington, DC area. The regulations are being revised to clarify instances where fees may be charged for services related to building use. It also updates contact information for requesting use of NARA public areas in the Washington, DC National Archives Building and the National Archives at College Park.

This proposed rule is not a significant regulatory action for the purposes of Executive Order 12866 and has been reviewed by the Office of Management and Budget (OMB). As required by the Regulatory Flexibility Act, it is hereby certified that this proposed rule will not have a significant impact on a substantial number of small entities. This proposed rule does not have any federalism implications.

List of Subjects in 36 CFR Part 1280

Archives and records.

For the reasons set forth in the preamble, NARA proposes to amend part 1280 of title 36, Code of Federal Regulations, as follows:

PART 1280—USE OF NARA FACILITIES

■ 1. The authority citation for part 1280 continues to read as follows:

Authority: 44 U.S.C. 2102 notes, 2104(a), 2112, 2903.

■ 2. Amend § 1280.78 by revising paragraph (c) to read as follows:

§ 1280.78 Does NARA charge fees for the use of public areas in the National Archives Building?

* * * * *

(c) Federal and quasi-Federal agencies, State, local, and tribal governmental institutions using public space for official government functions pay fees to the National Archives Trust Fund only for the costs for room rental, administrative fees, additional cleaning, security, and other staff services NARA provides.

■ 3. Amend § 1280.80 by revising paragraph (a) to read as follows:

§ 1280.80 How do I request to use NARA public areas in the National Archives Building?

(a) Direct your request to use space to Special Events (Partnerships Division), National Archives and Records Administration, 700 Pennsylvania Avenue NW, Washington DC 20408; or request by email to *specialevents@nara.gov.*

* * * * *

■ 4. Revise § 1280.87 to read as follows:

§ 1280.87 Does NARA charge fees for the use of public areas in the National Archives at College Park?

NARA may charge a fee under 44 U.S.C. 2903(b) for the use of public areas in the National Archives at College Park. We inform organizations in advance and in writing of the total estimated cost of using the public areas. Federal and quasi-Federal agencies, State, local, and tribal governmental institutions using public space for official government functions pay fees to the National Archives Trust Fund only for the costs for room rental, administrative fees, additional cleaning, security, and other staff services NARA provides.

■ 5. Amend § 1280.88 by revising paragraph (a) to read as follows:

§ 1280.88 How do I request to use NARA public areas in the National Archives at College Park?

(a) Direct your request to use space to Special Events (Partnerships Division), National Archives and Records Administration, 700 Pennsylvania Avenue NW, Washington DC 20408; or request by email to *specialevents@nara.gov.*

* * * * *

Dated: March 28, 2013.

David S. Ferriero,

Archivist of the United States.

[FR Doc. 2013–08020 Filed 4–4–13; 8:45 am]

BILLING CODE 7515–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 488 and 489

[CMS–3255–P]

RIN 0938–AQ33

Medicare and Medicaid Programs; Survey, Certification and Enforcement Procedures

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the survey, certification, and enforcement procedures related to CMS oversight of national accreditation organizations (AOs). These revisions would implement certain provisions under the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). The proposed revisions would also clarify and strengthen our oversight of AOs that apply for, and are granted, recognition and approval of an accreditation program in accordance with the Social Security Act.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on June 4, 2013.

ADDRESSES: In commenting, please refer to file code CMS–3255–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–3255–P, P.O. Box 8016, Baltimore, MD 21244–8016.

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–3255–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–8016.

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) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Cindy Melanson, (410) 786–0310; Patricia Chmielewski, (410) 786–6899; or Marilyn Dahl, (410) 786–8665.

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.

Acronyms

ADI—Advanced Diagnostic Imaging Services
AO—Accrediting Organization
ASC—Ambulatory Surgical Center
CAH—Critical Access Hospital
CfC—Condition for coverage
CFR—Code of Federal Regulations
CMHC—Community Mental Health Center
CMS—Center for Medicare & Medicaid Services
CoP—Condition of Participation
CORF—Comprehensive Outpatient Rehabilitation Facility
EMTALA—Emergency Medical Treatment and Labor Act
GAO—Government Accountability Office
HHA—Home Health Agency
HHS—Department of Health and Human Services
MIPPA—Medicare Improvements for Patients and Providers Act of 2008
NF—Nursing Facility
OIG—Office of the Inspector General
OPT—Provider of outpatient physical therapy and speech language pathology services
RHC—Rural Health Clinic
Social Security Act—the Act
SNF—Skilled Nursing Facility
TJC—The Joint Commission

I. Background

To participate in the Medicare program, providers and suppliers of health care services, must be substantially in compliance with specified statutory requirements of the Social Security Act (the Act), as well as any additional regulatory requirements related to the health and safety of patients specified by the Secretary of the Department of Health and Human Services (HHS). These health and safety requirements are generally called conditions of participation (CoPs) for most providers, requirements for skilled nursing facilities (SNFs), conditions for coverage (CfCs) for ambulatory surgical centers (ASCs) and other suppliers, and conditions for certification for rural health clinics (RHCs). A provider or supplier that does not substantially comply with the applicable health and safety requirements risks having its participation in the Medicare program terminated.

In accordance with section 1864 of the Act, state health departments or similar agencies, under an agreement with CMS, survey health care providers and suppliers to ascertain compliance with the applicable CoPs, CfCs, conditions of certification, or requirements, and certify their findings to us. Based on these state survey agency certifications, we determine whether the provider or supplier qualifies, or continues to qualify, for participation in the Medicare program.

Section 1865(a) of the Act allows health care facilities, except kidney

transplant centers, end stage renal dialysis facilities, and suppliers of medical equipment and supplies, to demonstrate compliance with Medicare CoPs, requirements, CfCs, or conditions for certification through accreditation by a CMS-approved program of a national accreditation body. If an accrediting organization (AO) is recognized by the Secretary as having standards for accreditation that meet or exceed Medicare requirements, any provider or supplier accredited by the AO's CMS-approved accreditation program may be deemed by us to meet the Medicare conditions or requirements.

We are responsible for the review, approval and subsequent oversight of national AOs' Medicare accreditation programs, and for ensuring providers or suppliers accredited by the AO meet the quality and patient safety standards required by the Medicare CoPs, requirements, CfCs, and conditions for certification. Any national AO seeking approval of an accreditation program in accordance with section 1865(a) of the Act must apply for and be approved by CMS for a period not to exceed 6 years. The AO must reapply for renewed CMS approval of an accreditation program before the date its approval period expires. This allows providers or suppliers accredited under the program to continue to be deemed to be in compliance with the applicable Medicare CoPs, requirements, CfCs, and conditions for certification. Regulations implementing these provisions are found at 42 CFR 488.1 through 488.9.

In accordance with § 488.8(f), if we determine that an AO's accreditation program requirements are no longer comparable to Medicare requirements we may open a deeming authority review and give the AO up to 180 days to adopt comparable requirements. If at the end of the deeming authority review period, the AO's accreditation program has failed to adopt comparable requirements, we may give the AO conditional approval with a probationary period for up to one year. Within 60 days after the end of any probationary period, we will make a final determination as to whether or not an accreditation program continues to meet the Medicare requirements and will issue an appropriate notice (including reasons for the determination) to the AO and affected providers or suppliers.

Section 1834(e) of the Act requires that, beginning January 1, 2012, Medicare payment may only be made for the technical component of advanced diagnostic imaging (ADI) services for which payment is made under the fee schedule established in section 1848(b) of the Act to a supplier who is accredited by an accrediting organization designated by the Secretary. Currently, oversight of these accrediting organizations is limited to requirements at § 414.68, and these accrediting organizations are not subject to the more expansive oversight requirements at 488, subpart A.

II. Provisions of the Proposed Rule

Section 125 of the Medicare Improvement for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275, enacted on July 15, 2008) removed legal distinctions between the Joint Commission (TJC) hospital accreditation program and all other accreditation programs approved by CMS in accordance with section 1865 of the Act. In this proposed rule, we are proposing corresponding changes to the regulations in part 488, subpart A, which implement section 1865 of the Act.

The Secretary has endorsed the recommendations of the HHS Office of Inspector General (OIG), and the Government Accountability Office (GAO) to strengthen our oversight and ensure greater accountability of AOs and instructed CMS to respond appropriately [1]. AOs and their CMS-approved accreditation programs significantly impact the health and safety of patients and the quality of care provided in Medicare-participating facilities across the country. We currently have 19 approved accreditation programs offered by seven national AOs. In fiscal year 2011, accredited facilities deemed to meet Medicare standards accounted for over 11,000 Medicare-participating facilities (not including accredited clinical laboratories.

All 19 CMS-approved AO accreditation programs received an extensive review in accordance with the application and reapplication process described at part 488 in recent years. The application and reapplication review process provides us the opportunity to conduct a comprehensive evaluation of an AO's performance and ability to assure that providers or suppliers meet or exceed the applicable Medicare standards. The review process also provides the opportunity to evaluate compliance with the other requirements of subpart A of part 488.

The high volume of comprehensive AO application and reapplication reviews that we have conducted has provided us with an abundance of opportunities to apply the existing AO approval regulations in a variety of circumstances. Throughout each review, we worked closely with the AOs, provided education and extensive feedback, and clarified expectations for the AOs. This experience has helped us to identify areas of our regulations in need of revision to more clearly articulate the requirements for all AOs with a CMS-approved accreditation program, as well as new AOs seeking initial CMS approval.

Furthermore, as we have taken actions to exercise more oversight of existing CMS-approved AO programs, we have become aware of the need to clarify, reorganize, and amend our regulations to support a more efficient and effective oversight process. In several situations involving serious and pervasive areas of non-compliance identified in CMS-approved AO accreditation programs, we found it necessary to invoke our oversight authorities under the existing regulations. In each case, we required the AO to implement corrective action(s) to ensure comparability with the Medicare requirements. Actions that we normally take include opening a deeming review outside the normal reapplication process, and issuing a conditional approval with a probationary period. In the course of taking these actions, we identify the need to revise and expand our enforcement tools to strengthen our ability to address serious and pervasive areas of AO non-compliance with the Medicare requirements; ensure that the AO takes the necessary corrective actions to address the area(s) of non-compliance; and ensure continuing compliance and comparability with Medicare requirements.

We propose expanding the scope of the accrediting organizations' oversight regulations at § 488, subpart A to include accrediting organizations with CMS-approved accreditation programs for ADI services. The current oversight regulations for accrediting organizations for the technical component of ADI services at § 414.68 would remain unchanged. This proposed expansion is part of our initiative to broaden our quality oversight of both the CMS-approved accrediting organizations as

[1] HCFA's Approval and Oversight of Private Accreditation Organizations (HEHS–99–197R), September 30, 1999. *http://www.gao.gov/products/HEHS–99–197R*

CMS Needs Additional Authority to Adequately Oversee Patient Safety in Hospitals (GAO–04–850) July 20, 2004. *http://www.gao.gov/new.items/d04850.pdf*

Hospital Oversight in Medicare: Accreditation and Deeming Authority. May 6, 2005 *http://www.nhpf.org/library/issue-briefs/IB802_Accreditation_05–06–05.pdf*

Moffett, M. & Bohara, A. Hospital Quality Oversight by the Joint Commission on Accreditation of Healthcare Organizations. Vol 31, No. 4 (Fall 2005) pp 629–647.

well as the suppliers of ADI services. As part of this effort, we anticipate future rule making to develop and implement Medicare health and safety standards for suppliers of these services. Prior to embarking upon this rule making process, we anticipate consulting with key stakeholders to shape the notice of proposed rulemaking. We note that, under section 135 of MIPPA, state survey agencies do not play a role in the oversight of suppliers of the technical component of ADI services, and we do not have the statutory authority to create such a role.

We propose to clarify that, when a state survey agency substantial allegation validation survey, that is, a complaint survey, of an accredited provider or supplier finds substantial non-compliance with one or more of Medicare's conditions or requirements, we have the flexibility in terms of its next steps. Currently we may either proceed immediately to enforcement action based on that complaint survey, or may instead require the state survey agency to conduct another, full survey which assesses compliance with all of the CoPs or CfCs for that type of provider or supplier. We are proposing not only to retain this flexibility but also to expand it, so that we could require the state survey agency to conduct another, more comprehensive survey, but not a full survey assessing compliance with all the CoPs or CfCs. This clarification supports the ability for us to make efficient use of survey resources while maintaining an effective enforcement process that is appropriate for each specific case.

A. Definitions (§ 488.1)

Section 488.1 sets forth definitions for terms used in part 488. We are proposing revisions at § 488.1 as follows:

- We propose deleting the definition of ''accredited provider or supplier.'' Use of this language has caused confusion both internally and externally. National AOs offer a variety of accreditation programs. However, not all programs are CMS-approved accreditation programs for the purpose of Medicare participation.
- We propose deleting the language, ''AOA stands for the American Osteopathic Association.'' The proposed revisions to subpart A would no longer refer to any specific AO. The proposed revisions instead are broader, referencing national AOs generically.
- We propose expanding the definition of ''certification'' to include the RHC conditions; clarify that each provider or supplier must meet its respective conditions or requirements to be certified; and deleting the language ''for SNFs and NFs'' to eliminate redundancy.
- We propose revising the definition of ''conditions for coverage'' for increased clarity and specificity.
- We propose adding a definition of ''conditions for certification'' to include the terminology for standards that RHCs must meet to participate in the Medicare program.
- We propose adding a definition of ''deemed status'' to increase clarity and reduce ambiguity when referring to the status of providers and suppliers accredited under a CMS-approved accreditation program and who are participating in Medicare via this accreditation.
- We propose revising the definition of ''full review'' to clarify that the regulations at part 488 apply to all providers and suppliers, not just hospitals.
- We propose adding a definition of ''immediate jeopardy'' at § 488.1 that would apply generically to all providers and suppliers subject to the certification requirements at part 488.
- We propose deleting the language, ''JCAHO stands for the Joint Commission on Accreditation of Healthcare Organizations,'' since the proposed revisions to subpart A do not refer to any specific AO.
- We propose adding a definition of ''national accreditation organization'' to specify that CMS requires a program seeking initial approval to already be fully implemented and operational nationally.
- We propose expanding the definition of ''provider of services or provider'' to include a clinic, rehabilitation agency or public health agency that furnishes outpatient physical therapy or speech language pathology services. This proposed change is consistent with the language at section 1861(p)(4) of the Act.
- We propose revising the definition of ''reasonable assurance by deleting the language ''taken as a whole.'' This proposed change would clarify the requirement that an AO's CMS-approved accreditation program has standards that meet or exceed the applicable Medicare conditions or requirements consistent with language at section 1865(a)(1) of the Act.
- We propose updating the definition of ''state survey agency'' for added clarity and precision.
- We propose revising the definition of ''substantial allegation of non-compliance'' to correct a previous error.
- We propose modifying the definition of ''supplier'' to make it consistent with the definition of supplier as amended by section 901 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173).
- We propose deleting the definition of ''validation review period.'' The concept of a fixed review period would not be used in the proposed revisions at § 488.8.

B. Statutory Basis (§ 488.2)

Section 488.2 sets forth the statutory basis for provider and supplier requirements. We propose revising this section by adding pertinent statutory citations and revising the statutory citation at section 1883 of the Act by replacing the title ''Requirements for hospitals that provide SNF care'' with ''Requirements for hospitals that provide extended care services'' to be consistent with the statutory language.

C. Conditions of Participation; Conditions for Coverage; Conditions for Certification; and Long-Term Care Requirements (§ 488.3)

Section 488.3 sets forth the conditions or requirements that a prospective provider or supplier must meet to be approved for participation in or coverage under the Medicare program. We propose revising § 488.3 to include the requirements RHCs must meet to participate in Medicare; the statutory citations for CAHs, RHCs, hospitals that provide extended care services, hospices, comprehensive outpatient rehabilitation facilities (CORFs), community mental health centers (CMHCs), providers of outpatient physical therapy and speech language pathology services (OPTs), and advanced diagnostic imaging services (ADIs); and the regulatory references for RHCs, CORFs, CMHCs, CAHs, OPTs, and ADIs. In addition, we propose to revise § 488.3(b) to address all providers or suppliers of services subject to certification. This proposal would also authorize the Secretary to consult with state survey agencies and other organizations, which would include all AOs and other national standard-setting organizations to develop Conditions of Participation. We are not proposing any policy changes to this program.

D. CMS-Approved National Accreditation Programs for Providers and Suppliers (§ 488.4)

We propose to revise § 488.4 as part of our effort to reorganize the application and reapplication process, delete redundancy, and reorganize the accreditation requirements in a more logical sequence. We are proposing revisions at § 488.4 as follows:

• Proposed § 488.4(a) would replace the requirements currently set out at § 488.6(a), with some modifications. The current regulation specifically lists the eligible provider and supplier accreditation programs under which AOs may provide us with reasonable assurance that the AO's requirements are at least as stringent as the Medicare conditions or requirements. We propose eliminating references to specific types of provider and supplier accreditation programs by simply stating that CMS-approved accreditation program for providers and suppliers with the exception of kidney transplant centers, end stage renal dialysis facilities, and suppliers of medical equipment and supplies may provide reasonable assurance to CMS that it requires providers and suppliers it accredits to meet the requirements that are at least as stringent as the Medicare conditions or requirements. Also, this section addresses national accreditation programs for hospitals other than those offered by TJC and AOA, as well as accreditation programs for other types of providers and suppliers. We propose deleting the reference to ''requirements concerning hospitals accredited by the JCAHO or AOA'' since the proposed changes are broader and would not specify any particular AO.

• Proposed § 488.4(b) would be a new provision, making it explicit that an AO's CMS-approved accreditation program would be approved in its entirety. Under this provision, an AO would not be permitted to make a recommendation to us for deemed status for a provider or supplier unless that provider or supplier satisfied all of the AO's requirements for accreditation. This would include both the AO accreditation program standards that may exceed the Medicare standards, as well as those that meet the Medicare standards.

E. Application and Reapplication Procedures for National Accreditation Organizations (§ 488.5)

We propose to revise § 488.5 to clarify the requirement that a prospective AO and its accreditation program be national in scope. We also propose moving the regulatory language currently at § 488.4 to § 488.5 with modifications as part of our effort to reorganize the accreditation requirements in a more logical sequence.

Specifically, we propose the following revisions:

• Proposed § 488.5(a) would replace the requirement currently set out at § 488.4(a). It would be revised to clarify that these provisions would apply to both initial applications for a new accreditation program, as well as re-approval of an existing CMS-approved accreditation program. The proposed revision further would clarify that each application for approval would pertain to a single provider/supplier-specific accreditation program.

• Proposed § 488.5(a)(1) would replace the requirement currently set out at § 488.4(a)(1), concerning the AO's identification in its application of the type of provider or supplier for which it is seeking approval. We propose revising this requirement to clarify that each application for our approval would be separate and distinct from applications for our approval of accreditation programs for other types of providers or suppliers.

• Proposed § 488.5(a)(2) would require an AO seeking initial CMS approval of a new accreditation program or renewed approval of an existing program to demonstrate that the program met the definition of a ''national accrediting organization.'' Section 1865 of the Act applies only to programs of national accreditation bodies. Demonstration must be specific to each accrediting program for which new or renewed CMS approval is sought. For example, an AO which has one or more existing CMS-approved programs that seek our initial approval of a new accreditation program must also demonstrate that the new program has been implemented nationally. This proposal implements the ''national'' requirement in the statute and sets forth a methodology for determining how an AO would meet the ''national'' qualification in the regulations.

• Proposed § 488.5(a)(3) would replace the requirement currently set out at § 488.4(a)(2), concerning the requirement that an AO submit a detailed comparison of its standards to Medicare requirements, and clarify the components of an acceptable crosswalk.

• Proposed § 488.5(a)(4) would replace the requirement currently set out at § 488.4(a)(3), which addresses the requirement that the AO must provide a detailed description of its survey process in its application for our approval of an accreditation program. The language of this provision would remain unchanged.

• Proposed § 488.5(a)(4)(i), would replace the requirement currently set out at § 488.4(a)(3)(i), concerning the frequency of surveys. The proposed revisions reflect existing CMS policy and would not impose any new requirements on AOs, but would be added to clarify the requirement.

• Proposed § 488.5(a)(4)(ii) is a new provision that would ensure surveys conducted by AOs were comparable to the Medicare requirements, and would implement section 1865(a)(2) of the Act.

• Proposed § 488.5(a)(4)(iii) would replace the requirement currently set out at § 488.4(a)(3)(ii). The language of this requirement would be unchanged and addresses the content and frequency of survey personnel training.

• Proposed § 488.5(a)(4)(iv) would replace the requirement currently set out at § 488.8(a)(2)(ii), requiring an AO to crosswalk its survey deficiency citations to the comparable Medicare requirements. This proposed provision is being modified for clarity to ensure consistency with existing policy and to ensure that our oversight of the AOs is effective. In addition, we are proposing that the language, ''and the ability to investigate and respond appropriately to accredited facilities,'' be redesignated to proposed § 488.5(a)(7).

• Proposed § 488.5(a)(4)(v) would replace the requirement currently set out at § 488.4(a)(3)(iii), concerning the survey review and accreditation decision-making process. We would delete language that would be redundant with language being incorporated into the proposed revised regulatory language at § 488.5(a)(8).

• Proposed § 488.5(a)(4)(vi), currently set out at § 488.4(a)(3)(iv), would specify that the AO's provider or supplier notification procedures meet or exceed those required for state survey agencies. This language represents existing CMS policy and would not impose any new requirements on AOs, but would be added to clarify the requirement and provide more specific and precise language.

• Proposed § 488.5(a)(4)(vii) is a new proposed provision regarding the AOs timeline and procedures for monitoring the facilities found to be out of compliance. This language reflects existing CMS policy and would not impose any new requirements on AOs, but would be added to clarify the requirement and provide more specific and precise language. Further, the proposed provision would be consistent with the requirement at section 1865(a)(2) of the Act.

• Proposed § 488.5(a)(4)(viii) would replace the requirement currently set out at § 488.8(a)(3), which requires the AO to provide a copy of its most recent accreditation survey for a specified provider or supplier, together with any other information related to the survey that we may require. We propose modifying this provision for consistency and clarity.

• Proposed § 488.5(a)(4)(ix) is a new proposed provision regarding AO notification to us when the AO

identifies an immediate threat to the health and safety of patients, that is, a situation that constitutes an immediate jeopardy as that term is defined in § 489.3. This provision would ensure that we are notified of situations that may put the health and safety of patients receiving care in Medicare-participating facilities at serious risk of harm, and would require us to take immediate action to enforce these provisions.

• Proposed § 488.5(a)(5) would replace the requirement currently set out at § 488.4(a)(4)(i). The language of this provision is unchanged and addresses the requirement that the AO provide us with detailed information about its surveyors.

• Proposed § 488.5(a)(6) would replace the requirement currently set out at § 488.4(a)(4)(i). This provision addresses the requirement for the AO to furnish information about the size and composition of its survey teams. The proposed expanded provisions would recognize that, within a given accreditation program, there can be great variation in the size and complexity of individual health care facilities. We believe that a uniform size and composition for the AO's survey teams would not be appropriate.

• Proposed § 488.5(a)(6) is a new proposed provision that would help ensure that an AO maintained an adequate number of trained surveyors to meet the demand for surveys, both initial and re-accreditation surveys. There have been instances where an AO could not maintain the required re-accreditation survey schedule interval for its existing accredited deemed status facilities because it was focusing its resources on meeting the demand of new customers for initial Medicare accreditation surveys. These AOs lacked sufficient personnel resources to handle both existing and new workloads.

• Proposed § 488.5(a)(7) would replace the requirement currently set out at § 488.4(a)(4)(ii) concerning the AO's education and experience requirements for its surveyors. The proposed revisions would explicitly require documentation of these surveyor requirements.

• Proposed § 488.5(a)(8) would replace the requirement currently set out at § 488.4(a)(iii) concerning in-service training of AO survey personnel. The language of this provision would be revised to explicitly state that the AO must provide documentation describing the content and frequency of this in-service training.

• Proposed § 488.5(a)(9) would replace the requirement currently set out at § 488.4(a)(4)(iv) concerning evaluation systems used by the AO to monitor the performance of individual surveyors and survey teams. This provision would be revised to explicitly state that an AO must provide documentation describing these evaluation systems.

• Proposed § 488.5(a)(10) would replace the requirement currently set out at § 488.4(a)(4)(v), concerning the AO's policies on the involvement of personnel in the survey or accreditation decision process who have a financial or professional affiliation with the provider or supplier. The provision would be modified to ensure that the AO has policies to avoid such potential conflicts of interest that could undermine the integrity of its accreditation program.

• Proposed § 488.5(a)(11) would replace the requirement currently set out at § 488.4(a)(5). This provision addresses the requirement that the AO provide information on its data management system in its application. We would reorganize the regulatory text to contain the provisions currently set out at § 488.5(a)(6)(i) and § 488.5(a)(6)(ii). In proposed § 488.5(a)(6), we would retain existing language requiring an AO to submit a description of its data management and analysis system regarding its surveys and accreditation decisions. The description would have to include the submission of the information set out at proposed § 488.5(a)(11)(i) and § 488.5(a)(11)(ii), which includes provider or supplier and survey information, and accreditation decisions.

• Proposed § 488.5(a)(11)(i) would require submission of a detailed description of how the AO uses its data system to assure compliance with the Medicare requirements. This new proposed language would replace existing language, which is being deleted. The existing language proposed for deletion is both too specific and too limiting in elaborating on what information would adequately convey how the AO uses its data management system for compliance purposes. The proposed language would make clear that we are seeking information on how the AO uses its data management systems to meet the various requirements of this subpart.

• Proposed § 488.5(a)(11)(ii) would modify the regulatory text currently at § 488.4(b)(1), which requires an AO to include in its application a written presentation of its ability to submit information electronically ''in ASCII comparable code.'' The reference to ASCII comparable code is outdated and insufficient. The proposed modifications are necessary to ensure that we have the required data to provide effective oversight of an approved accreditation program. We are also proposing to delete § 488.8(a)(2)(v), which is a redundant requirement related to electronic data submission in ASCII-comparable code.

• Proposed § 488.5(a)(12) would replace the requirement currently set out at § 488.4(a)(6). The language of this provision would remain unchanged and addresses the AO's procedures for responding to and investigating complaints.

• Proposed § 488.5(a)(13) would replace requirements currently set out at § 488.4(a)(7), with modifications. The current provision requires AOs to submit information to us regarding their policies and procedures for withholding, or removing accreditation status for facilities that fail to meet the AOs' standards or requirements. The AO must also report to us any other actions taken by the AO in response to its determination of non-compliance with its standards and requirements. We propose to expand this provision to require submission of the AOs' policies and procedures related to granting accreditation status and assignment of less than full accreditation status. Since the granting of full or less than full accreditation statuses are essential components of an AO's accreditation decision process, it is necessary for us to receive information on the policies and procedures pertaining to these types of decisions as well.

• Proposed § 488.5(a)(13)(i) would replace the requirement currently set out at § 488.4(a)(8). The current regulation addresses the requirement that AOs provide us a description of all types and categories of accreditation offered under its accreditation program. We would modify this provision by deleting language and terminology specific to one particular AO. Further, the current provision seems to require the AO to submit information on its accreditation programs that fall outside the parameters of its Medicare accreditation programs. Since we do not approve accreditation programs unrelated to Medicare, we believe that there is no reason to require AOs to submit such information to us, nor for us to have and review this non-relevant information.

• Proposed § 488.5(a)(13)(ii) would address the requirement, currently found at § 488.4(b)(3)(i), for an AO to agree, as a condition of approval, to notify us of any provider or supplier that has had its accreditation revoked, withdrawn, or revised, or has had any remedial or adverse action taken against

it. The current regulation requires the AO to notify us in writing within 30 days of its action. We propose to reduce this timeframe since AOs transmit such information to us electronically. The 30-day timeframe was based on information being sent to us via hard copy mail. Given the instantaneous nature of the electronic notification, as well as our need to learn of such adverse actions as soon as possible to initiate enforcement action as applicable, we believe it would be reasonable to require that the AO provide notice to us within three business days of its having taken the adverse action.

• Proposed § 488.5(a)(14) would replace the requirement currently set out at § 488.4(a)(9) concerning submission of information on currently accredited facilities as part of the AO's application. This provision would be modified for clarity. Proposed § 488.5(a)(15) would create a new requirement for an AO seeking renewed approval for a currently CMS-approved accreditation program. It would require such an AO to demonstrate, as a condition of acceptance of its application for renewal, that it demonstrated growth as evidenced by having accredited at least 50 health care facilities under its CMS-approved accreditation program. We believe that an established AO accreditation program that has not been able to accredit a minimum of 50 health care facilities since receiving initial CMS approval has failed to demonstrate sufficient infrastructure and scale to be sustained over a long period of time. Although we are willing to be flexible in accepting applications for initial approval from new national accreditation programs that are comparatively small, we believe that an established CMS-approved program that has not been able to accredit at least 50 healthcare facilities during the four-year period since its initial approval would have failed to demonstrate long term national viability. Further, we have limited resources available to conduct the detailed, comprehensive review of the AO's application required under section 1865(a)(2) of the Act. We believe these federal resources are best focused on those larger accreditation programs responsible for oversight of the quality of care provided in hundreds of accredited healthcare facilities, serving millions of patients, rather than on an accreditation program connected with a relatively small number of Medicare beneficiaries.

• Proposed § 488.5(a)(16) would replace the requirement currently set out at § 488.4(a)(10), which addresses the requirement for AOs to provide us with a list of accreditation surveys scheduled to be performed. We propose to revise this requirement to limit the schedule the AO must provide to surveys expected to be conducted during the six month period following submission of an application for CMS approval. Since we must complete the entire application review and publish a final notice announcing our decision within a 210 day statutory timeframe, it is not useful for a survey schedule to be submitted for a later timeframe. We use this survey schedule to plan our survey observation as part of our review. This requirement applies to both initial and renewal applications and is separate and apart from the requirement at proposed § 488.5(a)(11), regarding an approved program, for an AO to submit survey schedules as part of the data it agrees to provide us for our ongoing oversight.

• Proposed § 488.5(a)(17) would replace the requirement currently set out at § 488.4(b)(2), which requires an AO to provide a resource analysis demonstrating that it has the resources to support its accreditation program. The proposed modifications would more clearly identify the type of documentation an AO must provide to demonstrate the adequacy of its resources.

• Proposed § 488.5(a)(18) is a new provision that would address requirements related to AO written notification and timeframes regarding currently deemed providers or suppliers when the AO elected to terminate its CMS-approved accreditation program voluntarily. This provision would be necessary so that we could give affected state survey agencies and CMS Regional Offices adequate advance notice regarding the providers or suppliers affected by such a termination. In such a case, providers or suppliers would subsequently need to be surveyed and approved by the State survey agency, unless the providers or suppliers sought and received accreditation from another CMS-approved AO.

• Proposed § 488.5(a)(19) would replace the requirement currently set out at § 488.4(b)(3)(iii). This provision addresses the timeframe for AO notification to us regarding proposed changes in accreditation requirements. We are proposing to modify the regulation by expanding the timeframe to provide adequate time for us to conduct a comprehensive, detailed review of the AO's proposed changes. We are also proposing language clarifying that any proposed changes in a CMS-approved accreditation program may not be implemented by the AO before we approve such changes. This would ensure that the accreditation program continued to meet or exceed the Medicare requirements.

• Proposed § 488.5(a)(20) would replace the requirement currently set out at § 488.4(b)(3)(iv), concerning AO submission of changes to its standards within 30 days of a change in our requirements. We propose modifying the regulation text by deleting references to specific timeframes. This would provide us the flexibility to consider other factors when determining an appropriate timeframe for AOs to revise their program and submit the changes to us. These factors may include: the effective date of the applicable final rule, the effective date of our revised interpretive guidance or survey process, and the scope and magnitude of our changes that require corresponding AO changes. AOs would benefit from our having the flexibility to provide them longer timeframes for response, when appropriate. In addition, we propose adding language to ensure the AO program continues to meet or exceed the Medicare requirements, and specify the consequences for an AO's failure to submit timely comparable changes.

• Proposed § 488.5(a)(21) would replace the requirement currently set out at § 488.4(b)(3)(v), which concerns the requirement for the AO to permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings. We propose modifying the regulation by adding language to clarify the scope of the requirement.

• Proposed § 488.5(b) would replace the requirement currently set out at § 488.4(c). The language of this provision addresses the requirement that if we determine additional information is necessary to make a determination for approval or denial of an AO's application for deeming authority, the AO will be afforded the opportunity to provide the additional information. We propose deleting the language ''deeming authority.'' This language has been a source of confusion both internally and externally. It has led healthcare facilities and others to think that the AO awards deemed status and participation in Medicare. This proposed change clarifies that we have the authority to grant ''deemed status,'' not the AO.

• Proposed § 488.5(c)(1) would replace the requirement currently set out at § 488.4(f), which addresses the provision that an AO may withdraw its application at any time before the final notice is published in the **Federal Register**. We propose to modify this

provision by adding language clarifying that only an initial application can be withdrawn.

• Proposed § 488.5(c)(2) is a new requirement that addresses situations where an AO wishes to voluntary terminate its CMS-approved accreditation program. If an AO decides to voluntarily terminate its CMS-approved accreditation program, it must notify us of its decision and provide an effective date of termination. We will publish in the **Federal Register** a notice that includes the reason for the termination and the effective date. In accordance with the requirements at proposed § 488.8(e), the AOs must notify, in writing each of its providers or suppliers of its decision no later than 30 calendar days after the notice is published in the **Federal Register**. Proposed § 488.5(d) would replace the requirement currently set out at § 488.4(h), which addresses the ability of an AO whose request for approval of an accreditation program has been denied to resubmit its application if certain requirements are met. We would modify this provision by redesignating paragraph (i) to paragraph (e).

• Proposed § 488.5(d)(1) through § 488.5(d)(3), and § 488.5(e) would replace the requirement currently set out at § 488.4(h)(1) through § 488.4(h)(3)(i). The language of these provisions would be unchanged and addresses the requirements that an AO must meet to resubmit its application for CMS approval of an accreditation program after an initial request has been denied.

• Proposed § 488.5(f) is a new proposed provision, titled ''Notice and Comment,'' that would incorporate the timeframes for review of an AO request for CMS approval of an accreditation program that are set forth in section 1865(b) of the Act. The text currently at § 488.5 is being proposed for deletion because section 125 of MIPPA requires us to eliminate the separate provisions for TJC hospital accreditation.

• Proposed § 488.5(f)(1) would replace the requirement currently set out at § 488.8(b)(1), concerning publication of a proposed notice announcing our receipt of an AO application in the **Federal Register**. To better capture the purpose of a proposed versus a final notice, this provision would be revised by deleting language describing how the AO's accreditation program provides reasonable assurance that entities accredited by the organization meet the Medicare requirements, and moving it to the provision concerning the final notice at proposed § 488.5(f)(2)(i). In addition, language would be added related to the timeframe for public comment consistent with section 1865 of the Act.

• Proposed § 488.5(f)(2) would replace the requirement currently set out at § 488.8(b)(2), which requires us to publish a final notice announcing our decision to approve or disapprove an AO's accreditation program in the **Federal Register**. In accordance with section 1865(a)(3)(A) of the Act, the final notice must be published no later than 210 days after our receipt of a complete application. The language of the regulations would be streamlined and simplified to more clearly communicate existing requirements.

• Proposed § 488.5(f)(2)(i) would replace the requirement currently set out at § 488.8(b)(1), § 488.8(b)(2), and § 488.8(c), which address the contents of the final notice. We propose modifying the current timeframe requirement to be consistent with the provisions of section 1865(a)(3)(A) of the Act. Once a national AO's accreditation program is approved by us and this decision is published in the **Federal Register**, we may approve any provider or supplier that is surveyed or accredited for Medicare participation on or after the effective date of the final Notice (assuming that all other federal requirements have been met).

F. Providers or Suppliers That Participate in the Medicaid Program Under a CMS-Approved Accreditation Program (§ 488.6)

We propose to broaden and revise the standard's title as a conforming change consistent with section 125 of MIPPA. Proposed regulations at § 488.6 would replace the requirement currently set out at § 488.5(b), which states that eligibility for Medicaid participation can be established through Medicare deemed status for providers and suppliers that are not required under Medicaid regulations to comply with any requirements other than Medicare participation requirements.

G. Release and Use of Accreditation Surveys (§ 488.7)

We propose revising this standard's title to be more reflective of the standard's content. Proposed § 488.7 would replace the requirement currently set out at § 488.6(c)(1), which states that an accredited provider or supplier must authorize its AO to release a copy of its most current accreditation survey, together with any information related to the survey that CMS may require (including corrective action plans) to us and the state survey agency. The proposed revised requirement would be for the deemed provider to authorize release of a copy of its most recent accreditation survey to us. We are also taking this opportunity to clarify that we recognize that, in accordance with the Patient Safety Act and Quality Improvement Act (PSQIA) (Pub. L. 109–41) and implementing regulations at 42 CFR § 3.206(b)(8)(i) and (ii), an AO may not further disclose patient safety work product it receives when such work product complies with the requirements for patient safety work product protected under the PSQIA. Other proposed changes are part of our effort to reorganize and clarify the regulations, as follows:

• Proposed § 488.7(a) would replace the requirement currently set out at § 488.6(c)(2). The language of this requirement remains unchanged and addresses the requirement that we may determine that a provider or supplier does not meet the Medicare conditions on the basis of our own analysis of the accreditation survey or any other information related to the survey.

• Proposed § 488.7(b) would replace the requirement currently set out at § 488.5(c)(3) regarding our authority and discretion to disclose an AO survey and information related to the survey when the accreditation survey is related to an enforcement action taken by CMS. All other disclosures of AO survey information are prohibited under section 1865(b), with the exception of surveys of HHAs. This provision would be revised to clarify requirements for release of survey information.

H. On-Going Review of Accreditation Organizations (§ 488.8)

We propose modifying the title of this standard with language that is more specific and clarifies that our oversight of accreditation programs is continuous. We propose further revisions at § 488.8 consistent with our effort to reorganize, streamline and clarify the regulations, as follows:

• Proposed § 488.8(a) would replace the requirement currently set out at § 488.8(d), which address the continuing federal oversight of equivalency of an AO and removal of deeming authority. The proposed revisions would ensure consistency with section 1875(b) of the Act, which authorizes continuing Secretarial oversight of accreditation organization activities with respect to Medicare participating entities and yearly reports to Congress concerning such activities. The proposed revisions would replace the concept of a ''validation'' review with the broader concept of an ongoing AO ''performance'' review. We also propose to remove reference to a ''20 percent'' rate of disparity at current § 488.8(d)(2)(i) as a threshold for

triggering a validation review that could result in termination of an AO's program approval. Our experience over the past few years has demonstrated that, although the rate of disparity between AO and State survey agency surveys of the same facility within a 60 day time period may be one reliable measure of some aspects of AO performance, a single measure used in isolation does not provide a complete and accurate picture of AO performance. As described in the CMS annual report to Congress, ''Review of Medicare's Program for Oversight of Accreditation Organizations,'' we employ a multi-faceted approach that utilizes not only the disparity rate, but a number of other quantitative measures of AO performance, as well as the results of our periodic qualitative reviews of AO standards or of AO renewal applications to develop a comprehensive assessment of an AO's performance. We believe it is not appropriate to include in the regulation a requirement, based on only one data point, which would trigger an automatic, formal review of an AO's accreditation program's continuing approval. Likewise, we believe our ability to open a formal review of an AO program should not be limited by tying such review to one data point. As a result, we propose deleting the specific reference in the regulation to a 20 percent disparity rate triggering a formal validation review. We propose instead to provide at § 488.8(a) for an ongoing performance review of approved AO programs, and identify at proposed § 488.8(a)(2) the disparity rate as only one of several components that may trigger a performance review. Further, we propose in § 488.8(c) to provide for a formal accreditation program review when a performance review reveals evidence of substantial non-compliance. We believe that the proposed revision will enable us to continue to make use of the disparity rate in our ongoing assessment of AO performance, but to also make use of other performance indicators that enable us to reach a more comprehensive assessment of the quality of an AO's program. This revision would also make clearer that a formal accreditation program review could be opened as the result of a variety of serious compliance concerns.

- Proposed § 488.8(a)(1) through § 488.8(a)(3) are new proposed provisions which would be added to clarify that we evaluate AO performance by looking at various aspects of their practices.
- Proposed § 488.8(b) would revise the requirement currently set out at § 488.8(d)(1), which addresses CMS comparability reviews. The proposed revisions would clarify our current practice.
- Proposed § 488.8(b)(1) would revise the requirement currently set out at § 488.8(d)(1)(i), which address the need for a comparability review when we impose new requirements or change our survey process. We propose adding language which would provide us the flexibility to consider multiple factors when determining an appropriate timeframe for AOs to revise their accreditation program and submit revisions to CMS. These factors may include: the effective date of any final rule which would affect the substantive standards which are applied to various providers and suppliers; the effective date of any revised interpretive guidance or survey process affecting accredited providers or suppliers; and the scope and magnitude of such changes. In addition, the proposed new language would set out the consequences if an AO failed to submit comparable changes in a timely manner. These provisions would parallel proposed revisions at § 488.5(a)(12)(ii).
- Proposed § 488.8(b)(2) would revise the requirement currently set out at § 488.8(d)(1)(ii) concerning circumstances in which an AO proposes to adopt new requirements or changes its survey process. Under the current regulations, an AO must provide written notification to CMS at least 30 days in advance of the effective date of any proposed changes in its accreditation requirements or survey process. We propose expanding the timeframes to allow adequate time for us to conduct a comprehensive, detailed review of the AO's proposed changes. In addition, we propose adding language to clarify that the AO may not implement any changes to its CMS-approved accreditation program prior to receiving CMS approval. The purpose of the proposed new language would be to ensure continuing comparability of the AO's accreditation program with the Medicare requirements. These changes would parallel comparable changes at proposed § 488.5(a)(12)(i).
- Proposed § 488.8(c) and § 488.8(c)(1) would revise the requirement currently set out at § 488.8(e), which states that if a comparability or validation review indicates that an AO is not meeting the Medicare requirements, we will provide written notice to the AO indicating that its accreditation program approval may be in jeopardy and that an accreditation program review is being initiated. We propose revising the standard's title to more accurately reflect the language of the standard that follows and deleting redundant language. We would also add language to broaden the regulation and allow us to consider other aspects of AO performance that may warrant the opening of a review of a CMS-approved accreditation program. For example, if during a validation review, a question arose as to the ability of an AO to conduct re-accreditation surveys in a timely manner, or to provide us with timely and accurate data regarding deemed facilities, we would add this matter to the review. We further propose separating the one standard into two separate standards to more clearly articulate the circumstances that may trigger the opening of a review of a CMS-approved accreditation program and the written notice CMS must provide the AO upon opening such a review.
- Proposed § 488.8(c)(1)(i) would relocate the requirement currently set out at § 488.8(e)(1), which requires that our notice include a statement of the requirements, instances, rates or patterns of discrepancies that were found in the course of a comparability or validation review, as well as other related documentation associated with the review. We propose deleting language and replacing it with broader language that more clearly describes current practices related to an accreditation program review. The proposed revisions would address the information that we would be required to include in the written notice that we send the AO indicating that an accreditation program review is being initiated.
- Proposed § 488.8 (c)(1)(ii) would revise the requirement currently set out at § 488.8(e)(3), which requires that the notice of our comparability or validation review include a description of the process available if the AO wishes an opportunity to explain or justify the findings made during such review. The proposed language would clarify that the AO would not be limited to only one opportunity to offer factual information and documentation. Instead, such opportunities would be available throughout the accreditation program review process.
- Proposed § 488.8(c)(1)(iii) would revise the requirement currently set out at § 488.8(e)(4), which describes the possible enforcement actions that we may take based on findings from a validation review. We propose deleting the language, ''from the validation review,'' and replacing it with the conforming language, ''based on the findings of the accreditation program review.''
- Proposed § 488.8(c)(1)(iv) would revise the requirement currently set out

at § 488.8(f)(2). The current provision states that if CMS determines, following the accreditation program review, that the AO failed to adopt requirements comparable to CMS's, or to submit new requirements in a timely manner, the AO may be given conditional CMS approval of its accreditation program with a probationary period of up to 180 days to adopt comparable requirements. To clarify the existing requirements, we propose revising this provision to include the actions an AO would have to take to address the identified deficiencies, including a timeline for implementation not to exceed 180 calendar days from the date of issuance of the electronic version of the CMS letter, indicating that an accreditation program review is being initiated.

• Proposed § 488.8(c)(2) would revise the requirement currently set out at § 488.8(f)(1). The current provision requires CMS to conduct a review of an AO's accreditation program if the comparability or validation reviews produce findings that an AO has failed to adopt requirements comparable to Medicare. The language of this provision would be modified for increased clarity by utilizing current terminology.

• Proposed § 488.8(c)(3) would replace the requirement currently set out at § 488.8(f)(2). The current provision provides us authority to grant conditional approval of deeming authority with a probationary period of up to 180 days to adopt comparable requirements when the AO has failed to adopt requirements comparable to CMS's, or has failed to submit new requirements in a timely manner during a deeming review. We propose expanding the language to clarify that the probationary period of up to 180 calendar days would apply only when an AO has not adopted the necessary comparable changes to its existing CMS-approved accreditation program by the end of the 180-calendar-day accreditation program review. It further would clarify that an accreditation program review probationary period could not extend beyond the AO's term of approval. Finally, it would clarify the differences between an accreditation program review and renewal application review related to a probationary period, versus a conditional approval with a probationary period.

• Proposed § 488.8(c)(3)(i) would revise the requirement currently set out at § 488.8(f)(4), which states that within 60 days after the end of any probationary period, we will make a final determination as to whether or not an accreditation program continues to meet the Medicare requirements and will issue an appropriate notice to the AO and affected providers or suppliers. We propose clarifying this provision by deleting the language, ''make a final determination'' and replacing it with, ''issue a written determination.'' We further propose deleting the language, ''criteria described at paragraph (a)(1) of this section,'' and replacing it with, ''requirements of this subpart.''

• Proposed § 488.8(c)(3)(ii) would revise the requirement currently set out at § 488.8(f)(5) concerning the requirement that if the AO has not made improvements acceptable to us by the end of the probationary period, we will remove its approval effective 30 days from the date that it provides written notice to the AO. We propose modifying this provision by expanding the timeframe to account for the process required in order to publish a notice in the **Federal Register**.

• Proposed § 488.8(c)(3)(iii) would revise the requirement currently set out at § 488.8(f)(7), which instructs us to publish a notice in the **Federal Register** when necessary, withdrawing its approval of an AO's accreditation program, including a justification for its decision. We propose clarifying this provision by specifying the timeframe for publication of this notice.

• Proposed § 488.8(d) would revise the requirement currently set out at § 488.8(g), which state that when we determine that continued approval of an AO's accreditation program poses an immediate jeopardy to the patients of the entities accredited by that organization, or such continued approval otherwise constitutes a significant hazard to the public health, we may immediately withdraw approval of that AO's accreditation program. We propose clarifying this provision by deleting the language, ''deeming authority'' and replacing it with the conforming change, ''CMS-approved accreditation program.''

• Proposed § 488.8(e) is a new provision that would address an AO's responsibility to notify its providers or suppliers in the event that CMS withdraws approval of its accreditation program or the AO voluntarily terminates its program. This new, proposed provision would be necessary to ensure that providers or suppliers affected by an AO's loss of CMS approval for an accreditation program would be informed that they were no longer deemed to meet the Medicare requirements. Notification would afford affected providers or suppliers an opportunity to seek accreditation through another CMS-approved AO accreditation program, or participate in Medicare under the state survey agency's jurisdiction.

• Proposed § 488.8(f) would revise the requirement currently set out at § 488.8(h), which provides an AO that is not satisfied with CMS's determination to withdraw approval of its accreditation program the opportunity to request a reconsideration of that determination in accordance with subpart D of this part. We propose clarifying this provision by deleting the language, ''deeming authority'' and replacing it with the conforming change, ''CMS-approved accreditation program.''

• Proposed § 488.8(g) would revise the requirement currently set out at § 488.8(f)(8). The current requirement states that after we remove approval of an AO's accreditation program, an affected provider's or supplier's deemed status continues in effect for 60 days after removal of approval. It further states that we may extend the period for an additional 60 days if it determines that the provider or supplier submitted an application within the 60 day timeframe to another approved AO or to us so that compliance with Medicare conditions can be determined. We propose revising this provision by expanding the timeframe for continued deemed status of an affected provider or supplier if certain criteria are met, and the provider or supplier provides notice to the state survey agency to avoid duplication of services by the state survey agency and the AO.

• Proposed § 488.8(h) would replace the requirement currently set out at § 488.8(f)(9), which states that a provider's or supplier's failure to comply with the timeframes set forth will jeopardize its participation in the Medicare program and, where applicable, the Medicaid program. The language of this proposed provision would remain unchanged.

• Proposed § 488.8(i) would revise the requirement currently set out at § 488.9. This provision addresses the onsite observation of an AO's operations. We propose modifying this provision and adding language that provides greater specificity and clarity. In addition, we propose expanding the provision to give us greater flexibility in the timing of onsite visits to improve our oversight of approved AO accreditation programs.

I. Validation Surveys (§ 488.9)

We propose revising the title of this section because proposed § 488.9 sets out the language currently at § 488.7 that addresses validation surveys. The regulatory language would remain unchanged with the exception of: deleting language related to a plan of

correction that no longer reflects current state survey agency practice; and deleting language regarding compliance with the Life Safety Code that would be duplicative of proposed language at § 488.12(a)(2). In addition, we are proposing minor changes to conform this section to the rest of the proposed rule.

J. State Survey Agency Review: Statutory Provisions (§ 488.10)

We propose to revise § 488.10 to implement section 125 of MIPPA (revising section 1865(a) of the Act) to clarify that our proposed regulations apply to several types of providers and suppliers, not just hospitals. The regulation currently at § 488.10(c) addresses the authority of the Secretary to enter into agreements with state survey agencies for the purpose of conducting validation surveys. It further states, ''Section 1865(d) provides that an accredited hospital which is found after a validation survey to have significant deficiencies related to the health and safety of patients will no longer be deemed to meet the conditions of participation.'' We propose revising this provision by separating it into two separate provisions, § 488.10(c) and § 488.10(d). We propose modifying this provision by updating the regulatory citation to implement changes associated with section 125 of MIPPA. We further propose modifying this provision by adding broader language to make it clear that the regulations would apply to all national AOs with CMS-approved accreditation programs, and all provider or supplier types.

K. State Survey Agency Functions (§ 488.11)

We propose to revise § 488.11(b) by deleting the word, ''accredited,'' and replacing it with ''deemed'' as a conforming change for increased clarity. We also propose deleting the citation, ''§ 488.7,'' and replacing it with ''§ 488.9.'' This change would be consistent with the proposed reorganization of the requirements.

L. Effect of Survey Agency Certification (§ 488.12)

Section 488.12 addresses provider or supplier certification recommendations made by the state survey agency to CMS. Section 488.12(a)(2) addresses whether an accredited hospital is deemed to meet the Medicare CoPs or is subject to a full review by the state survey agency. We propose modifying this provision by inserting broader language to make it clear that the revised regulations not only pertain to hospitals exclusively, but to all deemed providers and suppliers. We further propose modifying this provision for clarity and conforming changes.

M. Loss of Accredited Status (§ 488.13)

Section 488.13 is a new proposed section entitled, ''Loss of Accreditation.'' We believe that this proposed section is necessary to address the consequences of a provider's or supplier's loss of accreditation, either voluntary or involuntary, from an AO's CMS-approved accreditation program. Voluntary loss of accreditation occurs when a provider or supplier chooses to withdraw from a CMS-approved accreditation program. Involuntary loss of accreditation occurs when an AO terminates a provider's or supplier's accreditation due to non-compliance with the AO's CMS-approved accreditation program requirements, or the provider's or supplier's non-payment of AO fees. The proposed additions address the timing of a state survey agency survey in such circumstances.

N. Providers or Suppliers, Other Than SNFs and NFs, With Deficiencies (§ 488.28)

We propose to revise § 488.28(a) to state that in immediate jeopardy situations involving providers or suppliers other than nursing homes or SNFs, the Secretary may require a shorter timeframe for a provider or supplier to come into compliance. This is consistent with our longstanding enforcement policy regarding immediate jeopardy situations with respect to provider types other than long term care facilities. We believe it would be beneficial to make this practice explicit in this proposed rule.

O. Statutory Basis (§ 489.1)

We propose to revise § 489.1(b), which addresses the scope of part 489. This proposed revision would expand the scope of these provisions to indicate that suppliers are subject to certification, as well as providers. Currently § 489.1(b) indicates that the regulations at § 489.13, governing the effective date of the provider agreement or supplier approval, are applicable not only to providers but also to suppliers that require certification in accordance with § 488.3 and § 488.12 to participate in Medicare. Various supplier-specific rules in this chapter that require certification also establish requirements related to termination of the supplier's participation agreement with the Medicare program. However, only some of these rules provide for termination of the agreement where the supplier places restrictions on the persons it will accept for treatment and fails to either exempt Medicare beneficiaries or apply the restrictions in the same way for Medicare beneficiaries as all other persons seeking care in the supplier facility. We believe that this non-discrimination provision should also apply as a basis for termination of all Medicare-certified suppliers.

Likewise, neither the certified supplier-specific rules governing termination of their agreements, nor the current termination of provider agreement rules at § 489.53 provide for termination of the supplier agreement where the certified supplier denies immediate access to state surveyors or other authorized entities or refuses to allow photocopying of its records. Currently, the only enforcement remedy in the face of such denial or refusal by a certified supplier would be exclusion of the certified supplier from Medicare by the OIG pursuant to 42 CFR § 1001.1301(a). It would be quicker and more efficient for us to handle such a denial or refusal of access to the certified supplier facility or photocopying of its records in the same manner as is currently used for providers, that is, CMS termination of the Medicare agreement.

Accordingly, we propose amending § 489.1(b) to expand the enumeration of provisions of part 489 that apply to certain suppliers, as well as providers. Because these provisions would apply only to those types of suppliers that require certification and not to all suppliers, we are including language in the proposed revised § 489.1(b) describing which types of suppliers would be affected, using the same language currently found at § 489.13. This language would indicate that the affected types of suppliers participate in Medicare based on surveys conducted by the state survey agency or CMS surveyors, or on the basis of accreditation by CMS-approved AO.

We propose redesignating the current language in § 489.1(b), which makes the effective date rules at § 489.13 applicable to suppliers as well as providers, as new paragraph § 489.1(b)(1). Further, we propose adding a new paragraph at § 489.1(b)(2) indicating that the termination provisions at § 489.53(a), § 489.53(a)(2), and § 489.53(a)(13) and proposed new § 489.53(a)(18) (discussed below) would apply to suppliers as well as providers.

P. Definitions (§ 489.3)

The regulations at § 489.3 define the term ''immediate jeopardy'' as a situation in which the provider's non-compliance with one or more requirements of participation has

caused, or is likely to cause, serious injury, harm, impairment, or death to a resident. This definition is identical to the one at § 488.301, which, in that context, applies only to long term care facilities, that is, nursing facilities (NFs) and SNFs. However, the regulation at § 489.53(d) addresses exceptions permitted for the required notice of termination which we must provide to the provider or supplier. This regulation permits exceptions in the case of immediate jeopardy situations in hospitals that have violated the Emergency Medical Treatment and Labor Act (EMTALA) requirements at § 489.24(a) through (e), as well as to immediate jeopardy situations in SNFs. We propose to revise the definition of immediate jeopardy at § 489.3 to clarify that it has the meaning found in proposed new § 488.1, which applies to all types of providers and suppliers subject to certification.

Q. Termination by CMS (§ 489.53)

We propose to revise § 489.53(a), which addresses the basis for us to terminate a Medicare provider agreement. We propose deleting the language ''with any provider'' from the heading for this provision since we are proposing that several of the termination provisions apply to suppliers, as well as providers. We propose retaining language stating that we may terminate the agreement with any provider if we find that any of the failings enumerated in § 489.53(a) is attributable to that provider. We further propose adding language indicating that we may, in addition to applying the various provisions in this chapter governing the termination of agreements with suppliers, terminate agreements with those suppliers that fail to comply with the requirements set out in § 489.53(a)(13) and proposed new § 489.53(a)(18).

We propose adding language in § 489.53(a)(2) to indicate that when a provider or supplier places restrictions on the persons accepted for treatment services without either exempting Medicare beneficiaries from such restrictions, or applying the restrictions to Medicare beneficiaries in the same manner as to all other persons seeking care, this may be grounds for termination of the Medicare agreement. The current language at § 489.53(a)(2) applies only to providers.

We propose adding language at § 489.53(a)(13) to indicate that failure by a provider or supplier to permit photocopying of any records or other information by, or on behalf of us, as necessary, to determine or verify compliance with participation requirements, may be grounds for terminating the Medicare agreement. The current language at § 489.53(a)(13) applies only to providers.

Further, we propose adding a new § 489.53(a)(18) to state explicitly that denial of immediate access to a state survey agency or other authorized entity for the purpose of determining, in accordance with § 488.3, whether the provider or supplier meets the applicable requirements, conditions of participation, conditions for coverage, or conditions for certification, may be grounds for termination of the provider agreement or supplier approval. Consistent with the definition at 42 CFR 1001.1301(a)(2), we interpret ''failure to grant immediate access'' to mean the failure to grant access at the time of a reasonable request or to provide a compelling reason why access may not be granted.

Finally, we propose a technical correction to § 489.53(d)(2)(i). Section 489.53(d) governs the timeframe for provision of a minimum 15-day advance notice of termination of a provider agreement by us to the affected provider, while subsection (d)(2) governs exceptions to the general timeframe in situations involving immediate jeopardy. The first exception, at § 489.53(d)(2)(i), applies to hospitals that have been determined by us to have an EMTALA violation which poses an immediate jeopardy. In these cases, we are required to give the hospital a preliminary notice of termination in 23 days if the hospital does not correct its identified deficiencies or refute the finding, and a final notice of termination at least 2, but not more than 4, days before the effective date of termination. We are proposing clarifying that this exception to the timing notice provision applies to a hospital that has been found to be in violation of any of the EMTALA requirements found at § 489.24, paragraphs (a) through (f). The current regulation refers to hospitals with emergency departments found in violation of § 489.24, paragraphs (a) through (e). This proposed clarification would not change current EMTALA citation or enforcement practices.

R. Table of Current Location and Proposed Location of Regulations Text

Table 1 identifies the current location, as well as the proposed location of the regulations text associated with this proposed rule.

TABLE 1—CURRENT LOCATION AND PROPOSED LOCATION OF REGULATIONS TEXT

Current location	Proposed location
§ 488.3(b)(1)	§ 488.3(b).
§ 488.4(b)	§ 488.5(a).
§§ 488.4(b)(3) and 488.4(b)(3)(i).	§ 488.5(a)(8)(ii).
§ 488.4(b)(3)(vii)	§ 488.5(a)(4)(ix).
§ 488.4(b)(3)(viii)	§ 488.5(a)(12)(ii).
§ 488.4(d)	§ 488.9.
§ 488.4(e)	§ 488.5(f)(1).
§ 488.6(a)	§ 488.4(a).
§ 488.4	§ 488.5.
§ 488.4(a)	§ 488.5(a).
§ 488.4(a)(1)	§ 488.5(a)(1).
§ 488.4(a)(2)	§ 488.5(a)(3).
§ 488.4(a)(3)	§ 488.5(a)(4).
§ 488.4(a)(3)(i)	§ 488.5(a)(4)(i).
§ 488.(a)(3)(ii)	§ 488.5(a)(4)(iii).
§ 488.8(a)(2)(ii)	§ 488.5(a)(4)(iv).
§ 488.4(a)(3)(iii)	§ 488.5(a)(4)(v).
§ 488.4(a)(3)(iv)	§ 488.5(a)(4)(vi).
§ 488.8(a)(3)	§ 488.5(a)(4)(viii).
§ 488.4(a)(4)(i)	§ 488.5(a)(5).
§ 488.4(a)(4)(i)	§ 488.5(a)(6).
§ 488.4(a)(4)(ii)	§ 488.5(a)(7).
§ 488.4(a)(4)(iii)	§ 488.5(a)(8).
§ 488.4(a)(4)(iv)	§ 488.5(a)(9).
§ 488.4(a)(4)(v)	§ 488.5(a)(10).
§ 488.4(a)(5)	§ 488.5(a)(11).
§ 488.4(b)(1)	§ 488.5(a)(11)(ii).
§ 488.4(a)(6)	§ 488.5(a)(12).
§ 488.4(a)(7)	§ 488.5(a)(13).
§ 488.4(a)(8)	§ 488.5(a)(13)(i).
§ 488.4(b)(3)(i)	§ 488.5(a)(13)(ii).
§ 488.4(a)(9)	§ 488.5(a)(14).
§ 488.4(a)(10)	§ 488.5(a)(16).
§ 488.4(b)(2)	§ 488.5(a)(17).
§ 488.4(b)(3)(iii)	§ 488.5(a)(19).
§ 488.4(b)(3)(iv)	§ 488.5(a)(20).
§ 488.4(b)(3)(v)	§ 488.5(a)(21).
§ 488.4(c)	§ 488.5(b).
§ 488.4(f)	§ 488.5(c).
§ 488.4(h)	§ 488.5(d).
§ 488.4(h)(1)-§ 488.4(h)(3)(i).	§ 488.5(d)(1)-§ 488.5(d)(3), § 488.5(e).
§ 488.8(b)(1)	§ 488.5(f)(1).
§ 488.8(b)(2)	§ 488.5(f)(2).
§ 488.8(b)(1), § 488.8(b)(2), § 488.8(c).	§ 488.5(f)(2)(i).
§ 488.5(b)	§ 488.6.
§ 488.6(c)(1)	§ 488.7.
§ 488.6(c)(2)	§ 488.7(a).
§ 488.5(c)(3)	§ 488.7(b).
§ 488.8(d)	§ 488.8(a).
§ 488.8(d)(1)	§ 488.8(b).
§ 488.8(d)(1)(i)	§ 488.8(b)(1).
§ 488.8(d)(1)(ii)	§ 488.8(b)(2).
§ 488.8(e)	§ 488.8(c)–§ 488.8(c)(1).
§ 488.8(e)(1)	§ 488.8(c)(1)(i).
§ 488.8(e)(3)	§ 488.8(c)(1)(ii).
§ 488.8(e)(4)	§ 488.8(c)(1)(iii).
§ 488.8(f)(2)	§ 488.8(c)(1)(iv).
§ 488.8(f)(1)	§ 488.8(c)(2).
§ 488.8(f)(2)	§ 488.8(c)(3).
§ 488.8(f)(4)	§ 488.8(c)(3)(i).
§ 488.8(f)(5)	§ 488.8(c)(3)(ii).
§ 488.8(f)(7)	§ 488.8(c)(3)(iii).
§ 488.8(h)	§ 488.8(d).
§ 488.8(g)	§ 488.8(e).

TABLE 1—CURRENT LOCATION AND PROPOSED LOCATION OF REGULATIONS TEXT—Continued

Current location	Proposed location
§ 488.8(f)(8)	§ 488.8(f).
§ 488.8(f)(9)	§ 488.8(f)(1).
§ 488.9	§ 488.8(g).
§ 488.7	§ 488.9.
§ 488.10(d)	§ 488.10(b).

III. Collection of Information Requirements

While this rule does contain information collection requirements, we believe they are exempt under 5 CFR 1320.3(c)(4). The requirements would affect less than 10 entities in a 12-month period. The requirements in the document have been in existence since September 2008. Since implementation, there have only been a total of seven entities that meet the criteria necessary to become accrediting organizations, with the seventh having just been added as recently as September 2008. Should the number of eligible entities approach or exceed 10, we will prepare an information collection request for OMB approval. As required by the Paperwork Reduction Act of 1995, we will announce the information collection request via the required **Federal Register** notices and allow the public ample time to review the request and submit comments.

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 Statement (or Analysis)

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This rule does not reach the economic threshold and thus is not considered a major rule.

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 governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $7.0 million to $35.5 million in any 1 year. Individuals and states are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this proposed rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Social Security 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 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this proposed rule 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 whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2013, that threshold level is currently approximately $141 million. This proposed rule has no consequential effect on state, local, or tribal governments or on the private sector.

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 488

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

■ 1. The authority citation for part 488 continues to read as follows:

Authority: Secs. 1102, and 1871 of the Social Security Act, unless otherwise noted (42 U.S.C 1302 and 1395(hh)); Section 6111 of the Patient Protection and Affordable Care Act (Pub. L. 111–148).

■ 2. Section 488.1 is amended by—

■ A. Revising the definitions of ''Certification,'' ''Full review,'' ''Provider of services or provider,'' ''Reasonable assurance,'' ''State survey agency,'' ''Substantial allegation of non-compliance,'' and ''Supplier.''

■ B. Removing the definitions of ''Accredited provider or supplier,'' ''AOA,'' ''JCAHO,'' and ''Validation review period.''

■ C. Adding the definitions of ''Conditions for certification,'' ''Deemed status,'' ''Immediate jeopardy,'' and ''National accrediting organization.''

The revisions and additions read as follows:

§ 488.1 Definitions.

* * * * *

Certification means a determination made by the state survey agency that providers and suppliers are in compliance with the applicable conditions of participation, conditions for coverage, conditions for certification, or requirements.

* * * * *

Conditions for certification means the health and safety standards RHCs must meet to participate in the Medicare program.

Deemed status is awarded by CMS when a provider or supplier has voluntarily applied for, and received, accreditation from a CMS-approved national accrediting organization; been recommended by the national accrediting organization for Medicare participation; has met all other

requirements for participation in the Medicare program as determined by CMS; and, is participating in the Medicare program on the basis of CMS's acceptance of the accrediting organization's recommendation. Deemed status is an alternative to regular surveys by the state survey agency to determine whether or not it continues to meet the Medicare requirements.

Full review means a survey of a provider or supplier for compliance with all of the Medicare conditions or requirements applicable to that provider or supplier type.

Immediate jeopardy means a situation in which the provider's or supplier's non-compliance with one or more Medicare requirements, conditions of participation, conditions for coverage or certification has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident or patient.

* * * * *

National accrediting organization means an organization that accredits health care facilities under a specific program and whose accredited healthcare facilities under each program are widely located geographically across the United States.

Provider of services or *provider* refers to a hospital, critical access hospital, skilled nursing facility, nursing facility, home health agency, hospice, comprehensive outpatient rehabilitation facility, or a clinic, rehabilitation agency or public health agency that furnishes outpatient physical therapy or speech pathology services.

* * * * *

Reasonable assurance means that an accrediting organization has demonstrated to CMS's satisfaction that its accreditation program requirements meet or exceed the Medicare program requirements.

* * * * *

State survey agency refers to the state health agency or other appropriate state or local agency CMS uses to perform survey and review functions provided for in sections 1864, 1819(g), and 1919(g) of the Act.

Substantial allegation of non-compliance means a complaint from any of a variety of sources (that is, patient, relative, or third party), including complaints submitted in person, by telephone, through written correspondence, or in newspaper or magazine articles, that, if substantiated, could or may affect the health and safety of patients or raise doubts as to a provider's or supplier's compliance with any Medicare condition of participation, condition for coverage, condition for certification, or other requirements.

Supplier means unless the context otherwise requires, a physician or other practitioner, a facility, or other entity (other than a provider of services) that furnishes items or services. For the purposes of this part, the term does not include suppliers of durable medical equipment and supplies, kidney transplant centers, or end stage renal dialysis facilities.

■ 3. Section 488.2 is amended by—

■ A. Adding the following statutory provisions in numerical order.

■ B. Revising the description of section 1883 of the Social Security Act.

The additions and revisions read as follows:

§ 488.2 Statutory basis.

* * * * *

1138(b)—Requirements for organ procurement organizations and organ procurement agencies.

* * * * *

1820—Requirements for CAHs.

1832(a)(2)(C)—Requirements for Organizations that provide outpatient physical therapy and speech language pathology services.

1832(a)(2)(F)—Requirements for ASCs.

1832(a)(2)(J)—Requirements for partial hospitalization for CMHCs.

1843(e)—Requirements for Advanced Diagnostic Imaging (ADI) services.

1861(e)—Requirements for hospitals.

* * * * *

1861(p)(4)—Requirements for rehabilitation agencies.

* * * * *

1861(aa)—Requirements for RHCs and FQHCs.

1861(cc)(2)—Requirements for CORFs.

1861(dd)—Requirements for hospices.

1861(ff)(3)(A)—Requirements for CMHCs.

* * * * *

1863—Consultation with state agencies, accrediting bodies, and other organizations to develop conditions of participation, conditions for coverage, conditions for certification, and requirements for providers or suppliers.

* * * * *

1875(b)—Requirements for performance review of CMS-approved accreditation programs.

1881—Requirements for ESRDs.

1883—Requirements for hospitals that furnish extended care services.

* * * * *

■ 4. Section 488.3 is revised to read as follows:

§ 488.3 Conditions of participation, conditions for coverage, conditions for certification and long term care requirements.

(a) *Basic rules.* To be approved for participation in, or coverage under, the Medicare program, a prospective provider or supplier must meet the following:

(1) Meet the applicable statutory definitions in section 1138(b), 1819, 1820, 1832(a)(2)(C), 1832(a)(2)(F), 1832(a)(2)(J), 1834(e), 1861, 1881, 1883, 1891, 1913 or 1919 of the Act.

(2) Be in compliance with the applicable conditions, certification requirements, or long term care requirements prescribed in part 405 subparts U or X, part 410 subpart E, § 410.33, § 414.68, part 416, part 418 subpart C, parts 482 through 485, part 491 subpart A, or part 494 of this chapter.

(b) *Special conditions*—The Secretary may consult with state agencies and other organizations to develop conditions of participation, conditions for coverage, conditions for certification, and long term care requirements.

(1) The Secretary may, at a state's request, approve health and safety requirements for providers or suppliers in the state that exceed Medicare program requirements.

(2) If a state or political subdivision imposes requirements on institutions (that exceed the Medicare program requirements) as a condition for the purchase of health services under a state Medicaid plan approved under title XIX of the Act, (or if Guam, Puerto Rico, or the Virgin Islands does so under a state plan for Old Age Assistance under title I of the Act, or for Aid to the Aged, Blind, and Disabled under the original title XVI of the Act), the Secretary imposes similar requirements as a condition for payment under Medicare in that state or political subdivision.

■ 5. Section 488.4 is revised to read as follows:

§ 488.4 General rules for a CMS-approved accreditation programs for providers and suppliers.

(a) A national accrediting organization can apply to CMS for approval to accredit providers and suppliers (except for kidney transplant centers, ESRD facilities, and suppliers of medical equipment and supplies) as meeting or exceeding the Medicare conditions or requirements. The following requirements apply when a national accrediting organization approved by CMS provides reasonable assurance to CMS that it requires providers or suppliers (except for kidney transplant centers, ESRD facilities, and suppliers of

medical equipment and supplies) it accredits to meet requirements that meet or exceed the Medicare conditions or requirements:

(1) When a provider or supplier demonstrates full compliance with all of the accreditation program requirements of the national accrediting organization's CMS-approved accreditation program, the national accrediting organization may recommend to CMS to grant deemed status to the provider or supplier.

(2) CMS may deem the provider or supplier to be in compliance with the applicable Medicare conditions or requirements. The provider or supplier is subject to validation surveys under § 488.9.

(b) [Reserved]

■ 6. Section 488.5 is revised to read as follows:

§ 488.5 Application and re-application procedures for national accrediting organizations.

(a) Information submitted with application. A national accrediting organization applying to CMS for approval or re-approval of an accreditation program under § 488.4 must furnish CMS with all of the following information and materials to demonstrate that the program provides reasonable assurance that the entities accredited under the program meet or exceed the applicable Medicare conditions or requirements. This information must include the following:

(1) Documentation that demonstrates the organization meets the definition of a ''national accrediting organization'' under § 488.1 as it relates to the accreditation program.

(2) The type of provider or supplier accreditation program for which the organization is requesting approval or re-approval.

(3) A detailed crosswalk (in table format) that identifies, for each of the applicable Medicare conditions or requirements, the exact language of the organization's comparable accreditation requirements and standards.

(4) A detailed description of the organization's survey process to confirm that a provider or supplier meets or exceeds the Medicare program requirements. This description must include all of the following information:

(i) Frequency of surveys performed and agreement by the organization to re-survey every accredited provider or supplier, through unannounced surveys, no later than 36 months after the previous accreditation survey, including an explanation of how the accrediting organization will maintain the schedule it proposes. If there is a statutorily-mandated survey interval of less than 36 months, the organization must indicate how it will adhere to the statutory schedule.

(ii) Documentation demonstrating the comparability of the organization's survey process and surveyor guidance to those required for state survey agencies conducting federal Medicare surveys for the same provider or supplier type, as specified in the CMS State Operations Manual (Pub. No. 100–07).

(iii) Copies of the organization's survey forms, guidelines, and instructions to surveyors.

(iv) Documentation demonstrating that the organization's survey reports identify, for each finding of non-compliance with accreditation standards, the comparable Medicare conditions of participation, conditions for coverage, conditions for certification, or requirements.

(v) Description of the organization's accreditation survey review process.

(vi) Description of the organization's procedures and timelines for notifying surveyed facilities of non-compliance with the accreditation program's standards.

(vii) Description of the organization's procedures and timelines for monitoring the provider's or supplier's correction of identified non-compliance with the accreditation program's standards.

(viii) A statement acknowledging that, as a condition for CMS approval of a national accrediting organization's accreditation program, the organization agrees to provide CMS with a copy of the most recent accreditation survey for a specified provider or supplier, together with any other information related to the survey as CMS may require (including corrective action plans).

(ix) A statement acknowledging that the accrediting organization will provide timely notification to CMS when an accreditation survey or complaint investigation identifies an immediate jeopardy as that term is defined at § 489.3 of this chapter. Using the format specified by CMS, the accrediting organization must notify CMS within 1 business day from the date the accrediting organization identifies the immediate jeopardy.

(5) The criteria for determining the size and composition of the organization's survey teams for the type of provider or supplier to be accredited, including variations in team size and composition for individual provider or supplier surveys.

(6) The overall adequacy of the number of the organization's surveyors, including how the organization will increase the size of the survey staff to match growth in the number of accredited facilities while maintaining re-accreditation intervals for existing accredited facilities.

(7) A description of the education and experience requirements surveyors must meet.

(8) A description of the content and frequency of the organization's in-service training it provides to survey personnel.

(9) A description of the organization's evaluation systems used to monitor the performance of individual surveyors and survey teams.

(10) The organization's policies and procedures for avoiding potential conflicts of interest by precluding individuals who are professionally or financially affiliated with a provider or supplier from participating in the survey or accreditation decision process with respect to that provider or supplier.

(11) A description of the organization's data management and analysis system with respect to its surveys and accreditation decisions, including all of the following:

(i) A detailed description of how the organization uses its data to assure the compliance of its accreditation program with the Medicare program requirements.

(ii) A statement acknowledging that the organization agrees to submit timely, accurate, and complete data to support CMS's evaluation of the accrediting organization's performance. The organization must submit to CMS the data according to the instructions and timeframes CMS specifies. Data submissions include, but are not limited to, accredited provider or supplier demographic information, survey schedules, survey findings, and notices of accreditation decisions.

(12) The organization's procedures for responding to, and investigating, complaints against accredited facilities, including policies and procedures regarding coordination of these activities with appropriate licensing bodies and ombudsmen programs.

(13) The organization's accreditation status decision-making process, including its policies and procedures for granting, withholding, or removing accreditation status for facilities that fail to meet the accrediting organization's standards or requirements, assignment of less than full accreditation status or other actions taken by the organization in response to non-compliance with its standards and requirements. The organization must furnish the following:

(i) A description of all types and categories of accreditation decisions associated with the program for which

approval is sought, including the duration of each.

(ii) A statement acknowledging that the organization agrees to notify CMS (in a manner CMS specifies) of any provider or supplier-specific accreditation decisions, including but not limited to the following: accreditation revoked, withdrawn, or revised; or has had any remedial or adverse action taken against it, within 3 business days from the date the organization takes an action.

(14) A list of all facilities currently accredited by the organization under the program for which CMS approval is sought, including the type and category of accreditation currently held by each provider or supplier, and the expiration date of each provider's or supplier's current accreditation.

(15) CMS considers applications for re-approval of a national accrediting organizations accreditation program if the accrediting organization demonstrates it has accredited at least 50 providers or suppliers under its current CMS-approved accreditation program.

(16) A schedule of all accreditation surveys expected to be conducted by the organization during the 6-month period following submission of the application.

(17) The three most recent audited financial statements of the organization that demonstrate that the organization's staffing, funding, and other resources are adequate to perform the required surveys and related activities.

(18) A statement that it will provide written notification to all providers or suppliers accredited under a CMS-approved accreditation program at least 90 calendar days in advance of the effective date of a decision by the organization to voluntarily terminate its CMS-approved accreditation program.

(19) A statement that it will provide written notification to CMS at least 60 calendar days in advance of the effective date of any proposed changes in the organization's CMS-approved accreditation program requirements, including an agreement not to implement the changes before receiving CMS's approval.

(20) A statement that, in response to a notice from CMS of a change in the applicable conditions or requirements or in the survey process, the organization will provide CMS with proposed corresponding changes in the organization's requirements for its CMS-approved accreditation program to ensure continued comparability with the CMS conditions or requirements or survey process. The organization must comply with the following requirements:

(i) The proposed changes must be submitted within 30 calendar days or by the date specified in the CMS notice, whichever is later.

(ii) The organization may not implement the proposed changes before receiving CMS's approval.

(21) A statement acknowledging that, as a condition for CMS's approval of an accreditation program, the organization will agree to require its surveyors to serve as witnesses in a legal proceeding if CMS takes an adverse action against a provider or supplier on the basis of the organization's accreditation survey findings.

(b) *Additional information needed.* If CMS determines that additional information is necessary to make a determination for approval or denial of the organization's initial application or re-application for CMS's approval of an accreditation program, CMS will notify the organization and afford it an opportunity to provide the additional information.

(c)(1) *Withdrawing an application.* An accrediting organization may withdraw its initial application for CMS's-approval of its accreditation program at any time before CMS publishes the final notice described in paragraph (f)(2) of this section.

(2) *Voluntary termination of a CMS-approved accreditation program.* An accrediting organization may voluntarily terminate its CMS-approved accreditation program at any time. The AO must notify CMS of its decision to voluntarily terminate its approved accreditation program and provide an effective date of termination. CMS will publish in the **Federal Register** a notice that includes the reasons for the termination and the effective date. In accordance with the requirements at § 488.8(e), the AOs must notify, in writing each of its providers or suppliers of its decision.

(d) *Requesting reconsideration of a disapproval.* If an accrediting organization has requested, in accordance with subpart D of this part, a reconsideration of CMS's determination that its request for approval of an accreditation program is denied, it may not submit an initial application for approval of an accreditation program for another type of provider or supplier until the hearing officer's final decision is rendered.

(e) *Re-submitting a request.* Except as provided in paragraph (d) of this section, an organization whose request for CMS's approval or re-approval of an accreditation program has been denied may resubmit its application if the organization completes all of the following:

(1) Revises its accreditation program to address the issues related to the denial of its previous request.

(2) Demonstrates that it can provide reasonable assurance that its accredited facilities meet the applicable Medicare program requirements.

(3) Resubmits the application in its entirety.

(f) *Public notice and comment.* CMS publishes a notice in the **Federal Register** when the following conditions are met:

(1) *Proposed notice.* When CMS receives a complete application from a national accrediting organization seeking CMS's approval of an accreditation program, it publishes a proposed notice. The proposed notice identifies the organization and the type of providers or suppliers to be covered by the accreditation program and provides 30 calendar days for the public to submit comments to CMS.

(2) *Final notice.* When CMS decides to approve or disapprove a national accrediting organization's application, it publishes a final notice within 210 calendar days from the date CMS determines the accrediting organization's application was complete. The final notice specifies the basis for the CMS decision.

(i) Approval or re-approval. If CMS approves or re-approves the accrediting organization's accreditation program, the final notice describes how the accreditation program provides reasonable assurance that the providers or suppliers accredited by the organization under that program meet the applicable Medicare requirements. The final notice specifies the effective date and term of the approval (which may not be later than the publication date of the notice and which will not exceed 6 years).

(ii) Disapproval. If CMS does not approve the accrediting organization's accreditation program, the final notice describes how the organization fails to provide reasonable assurance that the providers or suppliers accredited by the organization under that program meet the applicable Medicare requirements. The final notice specifies the effective date of the decision.

■ 7. Section 488.6 is revised to read as follows:

§ 488.6 Providers or suppliers that participate in the Medicaid program under a CMS-approved accreditation program.

A provider or supplier that has been granted ''deemed status'' by CMS by virtue of its accreditation from a CMS-approved accreditation program is eligible to participate in the Medicaid program.

§ 488.9 [Removed]

■ 8. Section 488.9 is removed.

§ 488.7 [Redesignated as § 488.9]

■ 9. Section 488.7 is redesignated as new § 488.9.

■ 10. New section 488.7 is added to read as follows:

§ 488.7 Release and use of accreditation surveys.

A Medicare participating provider or supplier deemed to meet program requirements in accordance with § 488.4 must authorize its accrediting organization to release to CMS a copy of its most current accreditation survey and any information related to the survey that CMS may require (including, but not limited to, corrective action plans).

(a) CMS may determine that a provider or supplier does not meet the applicable Medicare conditions or requirements on the basis of its own investigation of the accreditation survey or any other information related to the survey.

(b) With the exception of home health agency surveys, general disclosure of an accrediting organization's survey information is prohibited under section 1865(b) of the Act. CMS may publically disclose an accreditation survey and information related to the survey, upon written request, to the extent that the accreditation survey and survey information are related to an enforcement action taken by CMS.

■ 11. Section 488.8 is revised to read as follows:

§ 488.8 Ongoing review of accrediting organizations.

(a) *Performance review.* In accordance with section 1875(b) of the Act, CMS evaluates the performance of each CMS-approved accreditation program on an ongoing basis. This review includes, but is not limited to the following:

(1) Review of the organization's survey activity.

(2) Analysis of the results of the validation surveys under § 488.9(a)(1), including the rate of disparity between certifications of the accrediting organization and certifications of the state survey agency.

(3) Review of the organization's continued fulfillment of the requirements in § 488.5(a).

(b) *Comparability review.* CMS assesses the equivalency of an accrediting organization's CMS-approved program requirements to the comparable CMS requirements if the following conditions exist:

(1) CMS imposes new requirements or changes its survey process.

(i) CMS provides timely notice of the changes to the affected accrediting organization.

(ii) CMS specifies a timeframe, not less than 30 calendar days, for the accrediting organization to submit its proposed equivalent changes, including an implementation timeframe, for CMS review and approval.

(iii) After approval of the proposed changes, CMS determines whether the changes were implemented within the approved timeframe.

(iv) If an organization fails to submit timely comparable changes, CMS may open an accreditation program review in accordance with paragraph (c) of this section.

(2) An accrediting organization proposes to adopt new requirements or to change its survey process.

(i) An accrediting organization must provide written notice to CMS at least 60 calendar days before the proposed effective date of any proposed changes in its accreditation requirements or survey process.

(ii) The accrediting organization must not implement any changes before receiving CMS's approval.

(c) *CMS-approved accreditation program review.* If a comparability or performance review reveals evidence of substantial non-compliance of an accrediting organization's CMS-approved accreditation program with the requirements of this subpart, CMS may initiate an accreditation program review.

(1) If an accreditation program review is initiated, CMS provides written notice to the organization indicating that its CMS-approved accreditation program approval may be in jeopardy and that an accreditation program review is being initiated. The notice provides all of the following information:

(i) A statement of the instances, rates or patterns of non-compliance identified, as well as other related information, if applicable.

(ii) A description of the process to be followed during the review, including a description of the opportunities for the accrediting organization to offer factual information related to CMS's findings.

(iii) A description of the possible actions that may be imposed by CMS based on the findings of the accreditation program review.

(iv) The actions the accrediting organization must take to address the identified deficiencies including a timeline for implementation not to exceed 180 calendar days after receipt of the notice that CMS is initiating an accreditation program review.

(2) CMS reviews the accrediting organization's plan of correction for acceptability.

(3) If CMS determines as a result of the accreditation program review or a review of an application for renewal of an existing CMS-approved accreditation program that the accrediting organization has failed to meet any of the requirements of this subpart, CMS may place the accrediting organization's CMS-approved accreditation program on probation for a period up to 180 calendar days to implement corrective actions, not to exceed the accrediting organization's current term of approval. In the case of a renewal application where CMS has placed the accreditation program on probation, CMS indicates that any approval of the application is conditional while the program is placed on probation.

(i) Within 60 calendar days after the end of any probationary period, CMS issues a written determination to the accrediting organization as to whether or not a CMS-approved accreditation program continues to meet the requirements of this subpart, including the reasons for the determination.

(ii) If CMS has determined that the accrediting organization does not meet the requirements, CMS withdraws approval of the CMS-approved accreditation program. The notice of determination provided to the accrediting organization includes notice of the removal of approval, reason for the removal, including the effective date determined in accordance with paragraph (c)(3)(iii) of this section.

(iii) CMS publishes in the **Federal Register** a notice of its decision to withdraw approval of a CMS-approved accreditation program, including the reasons for the withdrawal, effective 60 calendar days from the date of publication of the notice.

(d) *Immediate jeopardy.* If at any time CMS determines that the continued approval of a CMS-approved accreditation program of any accrediting organization poses an immediate jeopardy to the patients of the entities accredited under that program, or the continued approval otherwise constitutes a significant hazard to the public health, CMS may immediately withdraw the approval of a CMS-approved accreditation program of that accrediting organization and publishes a notice of the removal, including the reasons for it, in the **Federal Register**.

(e) *Notification of providers or suppliers.* An accrediting organization whose CMS approval of its accreditation program has been withdrawn or the organization voluntarily terminates its program must notify, in writing, each of

its providers or suppliers of withdrawal of deemed status no later than 30 calendar days after the notices is published in the **Federal Register**.

(f) *Request for reconsideration.* Any accrediting organization dissatisfied with a determination to withdraw CMS approval of its accreditation program may request a reconsideration of that determination in accordance with subpart D of this part.

(g) *Continuation of deemed status.* After CMS removes approval of an accrediting organization's accreditation program, an affected provider's or supplier's deemed status continues in effect for 180 calendar days after the removal of the approval if the provider or supplier submits an application to another CMS-approved accreditation program within 60 calendar days from the date of publication of the removal notice in the **Federal Register**. The provider or supplier must provide written notice to the state survey agency that it has submitted an application for accreditation with deemed status with another CMS-approved accrediting organization within this same 60-calendar day timeframe. Failure to comply with the timeframe requirements specified in this section will place the provider or supplier under the state survey agency's authority for continued participation in Medicare and on-going monitoring.

(h) *Onsite observations of accrediting organization operations.* As part of the application review process, the ongoing review process, or the continuing oversight of an accrediting organization's performance, CMS may conduct at any time an onsite inspection of the accrediting organization's operations and offices to verify the organization's representations and to assess the organization's compliance with its own policies and procedures. The onsite inspection may include, but is not limited to, the review of documents, auditing meetings concerning the accreditation process, observation of surveys, the evaluation of survey results or the accreditation decision-making process, and interviews with the organization's staff.

■ 12. Newly designated § 488.9 is revised to read as follows:

§ 488.9 Validation surveys.

(a) *Basis for survey.* CMS may require a survey of an accredited provider or supplier to validate the accrediting organization's CMS-approved accreditation process. These surveys are conducted on a representative sample basis, or in response to substantial allegations of non-compliance.

(1) For a representative sample, the survey may be comprehensive and address all Medicare conditions or requirements, or it may be focused on a specific condition(s) as determined by CMS.

(2) For a substantial allegation, the state survey agency surveys for any condition(s) or requirement(s) that CMS determines is related to the allegations.

(b) *Selection for survey.* (1) A provider or supplier selected for a validation survey must cooperate with the state survey agency that performs the validation survey.

(2) If a provider or supplier selected for a validation survey fails to cooperate with the state survey agency, it will no longer be deemed to meet the Medicare conditions or requirements, but will be subject to a review by the state survey agency in accordance with § 488.10(a), and may be subject to termination of its provider agreement under § 489.53 of this chapter.

(c) *Consequences of a finding of non-compliance.* (1) If a CMS validation survey results in a finding that the provider or supplier is out of compliance with one or more Medicare conditions or requirements, the provider or supplier will no longer be deemed to meet the Medicare conditions or requirements and will be subject to ongoing review by the state survey agency in accordance with § 488.10(a) until the provider or supplier demonstrates compliance.

(2) CMS may take actions with respect to the deficiencies identified in the state validation survey in accordance with § 488.24, or may first direct the state survey agency to conduct another survey of the provider's or supplier's compliance with specified Medicare conditions or requirements before taking the enforcement actions provided for at § 488.24.

(3) If CMS determines that a provider or supplier is not in compliance with applicable Medicare conditions or requirements, the provider or supplier may be subject to termination of the provider or supplier agreement under § 489.53 of this chapter or of the supplier agreement in accordance with the applicable supplier conditions and any other applicable intermediate sanctions and remedies.

(d) *Re-instating deemed status.* An accredited provider or supplier will be deemed to meet the applicable Medicare conditions or requirements in accordance with this section if all of the following requirements are met:

(1) It withdraws any prior refusal to authorize its accrediting organization to release a copy of the provider's or supplier's current accreditation survey.

(2) It withdraws any prior refusal to allow a validation survey, if applicable.

(3) CMS finds that the provider or supplier meets all applicable Medicare conditions of participation, conditions for coverage, conditions of certification, or requirements.

(e) *Impact of adverse actions.* The existence of any performance review, comparability review, deemed status review, probationary period, or any other action by CMS, does not affect or limit conducting any validation survey.

■ 13. Section 488.10 is amended by revising paragraphs (b) through (d) to read as follows:

§ 488.10 State survey agency review: Statutory provisions.

* * * * *

(b) Section 1865(a) of the Act provides that if an institution is accredited by a national accrediting organization recognized by the Secretary, it may be deemed to have met the applicable conditions or requirements.

(c) Section 1864(c) of the Act authorizes the Secretary to enter into agreements with state survey agencies for the purpose of conducting validation surveys in institutions accredited by an accreditation program recognized by the Secretary.

(d) Section 1865(c) provides that an accredited institution that is found after a validation survey to have significant deficiencies related to health and safety of patients will no longer meet the applicable conditions or requirements.

■ 14. Section 488.11 is amended by revising paragraph (b) to read as follows:

§ 488.11 State survey agency functions.

* * * * *

(b) Conduct validation surveys of deemed facilities as provided in § 488.9.

* * * * *

■ 15. Section 488.12 is amended by revising paragraph (a)(2) to read as follows:

§ 488.12 Effect of survey agency certification.

* * * * *

(a) * * *

(2) A provider or supplier accredited under a CMS-approved accreditation program remains deemed to meet the Medicare conditions or requirements, or will be placed under the jurisdiction of the state survey agency and subject to further enforcement actions in accordance with the provisions at § 488.9.

* * * * *

■ 16. Section 488.13 is added to read as follows:

§ 488.13 Loss of accreditation.

If an accrediting organization notifies CMS that it is terminating a provider or supplier due to non-compliance with its CMS-approved accreditation requirements, the state survey agency will conduct a full review in a timely manner.

■ 17. Section 488.28 is amended by revising paragraph (a) to read as follows:

§ 488.28 Providers or suppliers, other than SNFs and NFs, with deficiencies.

(a) If a provider or supplier is found to be deficient in one or more of the standards in the conditions of participation, conditions for coverage, or conditions for certification or requirements, it may participate in, or be covered under, the Medicare program only if the provider or supplier has submitted an acceptable plan of correction for achieving compliance within a reasonable period of time acceptable to the Secretary. In the case of an immediate jeopardy situation, the Secretary may require a shorter time period for achieving compliance.

* * * * *

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

■ 18. The authority citation for part 489 is revised to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh).

■ 19. Section 489.1 is amended by revising paragraph (b) to read as follows:

§ 489.1 Statutory basis.

* * * * *

(b) Although section 1866 of the Act speaks only to providers and provider agreements, the following rules in this part also apply to the approval of supplier entities that, for participation in Medicare, are subject to a determination by CMS on the basis of a survey conducted by the state survey agency or CMS surveyors; or, in lieu of a state survey agency or CMS-conducted survey, accreditation by an accrediting organization whose program has CMS approval in accordance with § 488.4 at the time of the accreditation survey and accreditation decision, in accordance with the following:

(1) The effective date rules specified in § 489.13.

(2) The requirements specified in § 489.53(a)(2), (13), and (18), related to termination by CMS of participation in Medicare.

* * * * *

■ 20. Section 489.3 is amended by revising the definition of ''Immediate jeopardy'' to read as follows:

§ 489.3 Definitions.

* * * * *

Immediate jeopardy means a situation in which the provider's or supplier's non-compliance with one or more requirements, conditions of participation, conditions for coverage, or certification has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident or patient.

* * * * *

■ 21. Section 489.53 is amended by—

■ A. Revising paragraphs (a) introductory text, (a)(2), (a)(13).

■ B. Adding reserved paragraph (a)(17).

■ C. Adding paragraph (a)(18).

■ D. Revising paragraph (d)(2)(i) introductory text.

The additions and revisions read as follows:

§ 489.53 Termination by CMS.

(a) *Basis for termination of agreement.* CMS may terminate the agreement with any provider if CMS finds that any of the following failings is attributable to that provider, and may, in addition to the applicable requirements in this chapter governing the termination of agreements with suppliers, terminate the agreement with any supplier to which the failings in paragraphs (a)(2), (a)(13), and (a)(18) of this section are attributable:

* * * * *

(2) The provider or supplier places restrictions on the persons it will accept for treatment and it fails either to exempt Medicare beneficiaries from those restrictions or to apply them to Medicare beneficiaries the same as to all other persons seeking care.

* * * * *

(13) The provider or supplier refuses to permit photocopying of any records or other information by, or on behalf of, CMS, as necessary to determine or verify compliance with participation requirements.

* * * * *

(17) [Reserved]

(18) The provider or supplier fails to grant immediate access upon a reasonable request to a state survey agency or other authorized entity for the purpose of determining, in accordance with § 488.3, whether the provider or supplier meets the applicable requirements, conditions of participation, conditions for coverage or conditions for certification.

* * * * *

(d) * * *

(2) * * *

(i) *Hospitals.* If CMS finds that a hospital is in violation of § 489.24 (a) through (f), and CMS determines that the violation poses immediate jeopardy to the health or safety of individuals who present themselves to the hospital for emergency services, CMS—

* * * * *

CMS–3255–P

Authority: (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: November 15, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: March 13, 2013.

Kathleen Sebelius,

Secretary.

[FR Doc. 2013–07950 Filed 4–4–13; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 155

[CMS–9955–P]

RIN 0938–AR75

Patient Protection and Affordable Care Act; Exchange Functions: Standards for Navigators and Non-Navigator Assistance Personnel

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: The proposed regulations would create conflict-of-interest, training and certification, and meaningful access standards applicable to Navigators and non-Navigator assistance personnel in Federally-facilitated Exchanges, including State Partnership Exchanges, and to non-Navigator assistance personnel in State-based Exchanges that are funded through federal Exchange Establishment grants. These proposed standards would help ensure that Navigators and non-Navigator assistance personnel will be fair and impartial and will be appropriately trained, and that they will provide services and information in a manner that is accessible.

The proposed regulations would also make two amendments to the existing regulation for Navigators that would apply to all Navigators in all Affordable Insurance Exchanges (Exchanges), including State-based Exchanges, clarifying that any Navigator licensing, certification, or other standards

prescribed by the state or Exchange must not prevent the application of the provisions of title I of the Affordable Care Act; and adding to the list of entities ineligible to become Navigators, those entities with relationships to issuers of stop loss insurance, including those who are compensated directly or indirectly by issuers of stop loss insurance in connection with enrollment in Qualified Health Plans or non-Qualified Health Plans. The proposed regulations would also clarify that the same ineligibility criteria that apply to Navigators would also apply to non-Navigator assistance personnel providing services in any Federally-facilitated Exchanges, including in State Consumer Partnership Exchanges, and to federally funded non-Navigator assistance personnel in State-based Exchanges.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on May 6, 2013.

ADDRESSES: In commenting, please refer to file code CMS–9955–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 ''Submit a comment'' instructions.

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–9955–P, P.O. Box 8010, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–9955–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period: 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, call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Joan Matlack, (888) 393–2789.

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 (800) 743–3951.

I. Background

A. Introduction

The Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted on March 23, 2010; the Health Care and Education Reconciliation Act (Pub. L. 111–152) was enacted on March 30, 2010. These laws are collectively known as the Affordable Care Act.

Beginning on October 1, 2013, individuals and small businesses will be able to purchase private health insurance through state-based competitive marketplaces called Affordable Insurance Exchanges (Exchanges), also known as the Health Insurance Marketplaces.

The Exchanges will provide competitive marketplaces where individuals and small employers can compare available private health insurance options on the basis of price, quality, and other factors. The Exchanges, which will offer coverage that is effective beginning on January 1, 2014, will help enhance competition in the health insurance market, improve choice of affordable health insurance, and give small businesses the same purchasing power as large businesses.

Pursuant to sections 1311(b) and 1321(b) of the Affordable Care Act, each state has the opportunity to establish an Exchange that—(1) Facilitates the purchase of insurance coverage by qualified individuals through Qualified Health Plans (QHPs); (2) assists qualified employers in the enrollment of their employees in QHPs; and (3) meets other standards specified in the Affordable Care Act. These are referred to as State-Based Exchanges.

Section 1321(c)(1) of the Affordable Care Act requires the Secretary of HHS (''Secretary'') to establish and operate Exchanges within states that either: (1) do not elect to establish an Exchange, or (2) as determined by the Secretary on or before January 1, 2013, will not have an Exchange operational by January 1, 2014. These HHS-operated Exchanges are referred to as Federally-facilitated Exchanges. The Secretary has also explained through sub-regulatory guidance that these Federally-facilitated Exchanges may include State Partnership Exchanges in which states may assume significant responsibility for key Exchange functions.[1] Generally, a State Partnership Exchange will take one of two forms: a State Plan Management Partnership Exchange, or a State Consumer Partnership Exchange (Consumer Partnership Exchange).

Consumers can receive assistance from a variety of sources when seeking access to health insurance coverage through an Exchange. Sections 1311(d)(4)(K) and 1311(i) of the Affordable Care Act, and the regulation implementing those provisions, 45 CFR

[1] *See* 77 FR 18310, 18325–26 (Mar. 27, 2012); General Guidance on Federally-facilitated Exchanges (May 16, 2012) at *http://cciio.cms.gov/resources/files/ffe-guidance-05–16–2012.pdf;* and Guidance on the State Partnership Exchange (Jan. 3, 2013) at *http://cciio.cms.gov/resources/files/partnership-guidance-01–03–2013.pdf.*

155.210, direct all Exchanges to award grants to Navigators that will provide fair and impartial information to consumers about health insurance, the Exchange, QHPs, and insurance affordability programs including premium tax credits, Medicaid and the Children's Health Insurance Program (CHIP); and that will provide referrals to consumer assistance programs (CAP) and health insurance ombudsmen for enrollees with grievances, complaints, or questions about their health plan or coverage. Navigators are an important resource for all consumers, particularly communities that are under-served by and under-represented in the current health insurance market. Navigators will not make eligibility determinations and will not select QHPs for consumers or enroll applicants into QHPs, but will help consumers through the eligibility and enrollment process. The Exchange regulations, at 45 CFR 155.400(a), state that ''[t]he *Exchange* must accept a QHP selection from an applicant * * * and must—(1) Notify the issuer of the applicant's selected QHP; and (2) Transmit information necessary to enable the QHP issuer to enroll the applicant'' (emphasis added). Additionally, as articulated in 45 CFR § 155.310(d), the Exchange is responsible for making eligibility determinations. Taken together, these regulations clearly mean that the Exchange, not Navigators, must determine eligibility and enroll applicants into QHPs. Additionally, a Navigator cannot make the decision for an applicant as to which QHP to select. That said, Navigators may play an important role in facilitating a consumer's enrollment in a QHP by providing fair, impartial, and accurate information that assists consumers with submitting the eligibility application, clarifying the distinctions among QHPs, and helping qualified individuals make informed decisions during the health plan selection process.

The Exchange regulations also authorize Exchanges to perform certain consumer service functions in addition to the Navigator program. Federal regulations at 45 CFR § 155.205(d) and (e) provide that each Exchange must conduct consumer assistance activities as well as outreach and education activities to educate consumers about the Exchange and insurance affordability programs to encourage participation. The activities under § 155.205(d) and (e) include, but are not limited to, the Navigator grant program. Establishing a non-Navigator consumer assistance program pursuant to § 155.205(d) and (e) will help ensure that the Exchange is providing outreach, education, and assistance to as broad a range of consumers as possible so that all consumers can receive help when accessing health insurance coverage through an Exchange.

A program established to fulfill the consumer assistance, education, and outreach functions under § 155.205(d) and (e) through in-person consumer support, other than a Navigator program, is referred to in the proposed regulation and in this preamble as a ''non-Navigator assistance program authorized by § 155.205(d) and (e)'' or more simply as a ''non-Navigator assistance program.'' In addition, we refer to persons carrying out these consumer assistance, education, and outreach functions under § 155.205(d) and (e) as ''non-Navigator assistance personnel carrying out consumer assistance functions under § 155.205 (d) and (e)'' or ''non-Navigator entities or individuals authorized to carry out consumer assistance functions under § 155.205 (d) and (e)'' or more simply as ''non-Navigator assistance personnel.'' Non-Navigator assistance programs include what have sometimes been referred to as ''in-person assistance programs.'' Similarly, non-Navigator assistance personnel include what have sometimes been referred to as ''in-person assistance personnel.'' Therefore, when references are made in this preamble or in the proposed regulation to non-Navigator assistance programs or non-Navigator assistance personnel, those references also apply to in-person assistance programs or in-person assistance personnel, respectively.

State-based Exchanges may, but need not, establish non-Navigator assistance programs to provide consumer assistance, education, and outreach under § 155.205(d) and (e). Additionally, as a condition of a state's participation in a Consumer Partnership Exchange, the state will establish and operate a non-Navigator assistance program in a way that is consistent with the policies and interpretations HHS adopts for § 155.205(d) and (e) for the Federally-facilitated Exchanges. This does not affect the obligation of a Consumer Partnership Exchange to establish and operate a Navigator program, however. HHS will have responsibility for the inherently governmental function of awarding federal Navigator grants for the Federally-facilitated Exchanges, including State Partnership Exchanges. Federally-facilitated Exchanges, other than Consumer Partnership Exchanges, do not anticipate including a non-Navigator assistance program.

Section 1311(i)(6) prohibits Exchanges from using section 1311(a) grant funds to fund Navigator grants. However, section 1311(a) grant funds may be used to cover the Exchange's cost of administering the Navigator program, including, for example, the cost of Navigator training, grants management, and oversight.

State-based Exchanges and state partners in Consumer Partnership Exchanges may use section 1311(a) Exchange Establishment grants to fund non-Navigator assistance programs consistent with the following discussion.

Together, section 1311(a)(4)(B) and section 1311(d)(5)(A) provide that, as long as grant funds under section 1311(a) are available to the state, a State-based Exchange need not be self-sustaining during its initial year of operation. Accordingly, as long as section 1311(a) grant funds are available to the state, a State-based Exchange may not have sufficient funds independent of section 1311(a) grant funds during its initial year of operation to achieve all of the goals of the Navigator program. As a transitional policy in such circumstances, a State-based Exchange may use a non-Navigator assistance program in its initial year of operation to fill in any gaps in its Navigator program and otherwise ensure that the full range of services that its Navigator program will provide in subsequent years are provided during its initial year of operation. As the State-based Exchange becomes self-sustaining, the roles of the non-Navigator assistance program and the Navigator program may change. We note that, after the State-based Exchange becomes self-sustaining, the State-based Exchange can choose to establish or continue a non-Navigator assistance program, as a supplement to its fully-funded Navigator program. Similarly, a State-based Exchange that is self-sustaining from the outset, because section 1311(a) grant funds are no longer available to the state, can make a similar choice. In both such circumstances, the non-Navigator assistance program would have to be funded through some source other than section 1311(a) grant funds.

Section 1311(a) grant funds are available for non-Navigator assistance programs in Consumer Partnership Exchanges because the state has elected to establish and operate outreach, educational, and assistance activities to assist in its transition to a State-based Exchange, as a condition of its participation in the Consumer Partnership Exchange. Such activities do not purport to, nor do they in fact, supplant the obligation of the federal

government to establish a Navigator program. When a state partner in a Consumer Partnership Exchange transitions to a State-Based Exchange, the discussion of State-Based Exchanges above will apply.

While section 1311(i)(1) directs that the Navigator program be a grant program, State-based Exchanges and state partners in a Consumer Partnership Exchange have the flexibility to build a non-Navigator assistance program through contracts, direct hiring, or grants, subject to state law. Utilizing funding mechanisms other than grants for non-Navigator assistance programs may be particularly important to ensure that State-based Exchanges have enhanced flexibility to utilize non-Navigator assistance personnel to fill in any gaps in their Navigator programs or to appropriately supplement their Navigator program, as described above, by, for example, serving communities that may not be reached by their Navigator program.

B. Legislative and Regulatory Overview

Section 1311 of the Affordable Care Act generally establishes the creation of Exchanges and outlines various requirements and standards Exchanges must satisfy. Specifically, pursuant to sections 1311(b) and 1321(b) of the Affordable Care Act, each state has the opportunity to establish an Exchange.

Sections 1311(d)(4)(K) and 1311(i) of the Affordable Care Act direct each Exchange to establish a program under which it awards grants to Navigators who will carry out a list of required duties. A final rule implementing sections 1311(d)(4)(K) and 1311(i) of the Affordable Care Act was published on March 27, 2012 (77 FR 18310), and is codified at 45 CFR § 155.210.

Section 1311(i)(3) of the Affordable Care Act lists the duties Navigators must perform. Section 155.210(e) interprets these duties to include: maintaining expertise in eligibility, enrollment, and program specifications; conducting public education activities to raise awareness about the Exchange; providing information and services in a fair, accurate, and impartial manner, including information that acknowledges other health programs such as Medicaid and CHIP; facilitating selection of a QHP; providing referrals for consumers with questions, complaints, or grievances to any applicable office of health insurance consumer assistance or health insurance ombudsman established under section 2793 of the Public Health Service Act (PHS Act), or any other appropriate state agency or agencies; providing information in a culturally and linguistically appropriate manner, including to persons with limited English proficiency; and ensuring accessibility and usability of Navigator tools and functions for persons with disabilities.

Section 1311(i)(4) directs the Secretary to establish standards for Navigators, including provisions to ensure that any entity selected as a Navigator is qualified, and licensed if appropriate, to engage in the Navigator activities required by the law and to avoid conflicts of interest. 45 CFR 155.210(b)(1), which interprets this provision, directs each Exchange to ''develop and publicly disseminate * * * [a] set of standards, to be met by all entities and individuals awarded Navigator grants, designed to prevent, minimize and mitigate any conflicts of interest, financial or otherwise, that may exist for an entity or individuals to be awarded a Navigator grant and to ensure that all entities and individuals carrying out Navigator functions have appropriate integrity.'' Additionally, 45 CFR 155.210(c)(1)(iv) provides that a Navigator must not have a conflict of interest during its term as Navigator. 45 CFR 155.210(b)(2) directs Exchanges to develop and disseminate a set of training standards, to be met by all entities and individuals carrying out Navigator functions, to ensure Navigator expertise in the needs of underserved and vulnerable populations; eligibility and enrollment rules and procedures; the range of QHP options and insurance affordability programs; and privacy and security requirements applicable to personally identifiable information. This proposal develops and disseminates standards under § 155.210(b)(1) and (2) for the Federally-facilitated Exchanges, including State Partnership Exchanges, and for non-Navigator assistance personnel in State-based Exchanges that are funded through federal Exchange Establishment grants. These standards could also be used by State-based Exchanges at their discretion for their Navigator programs and for any non-Navigator assistance programs not funded with 1311(a) Exchange Establishment grants.

45 CFR 155.210(c)(1)(iii) also interprets section 1311(i)(4), and directs that entities or individuals must meet any licensing, certification, or other standards prescribed by the state or Exchange, if applicable, in order to receive a Navigator grant.

Section 1311(i)(4) of the Affordable Care Act also specifies that under the standards established by the Secretary, Navigators shall not be health insurance issuers or receive any consideration directly or indirectly from any health insurance issuer in connection with the enrollment of any qualified individuals or employees of a qualified employer in QHPs. 45 CFR § 155.210(d), which interprets this provision, prohibits Navigators from being health insurance issuers. It also provides that Navigators should not receive any compensation directly or indirectly from health insurance issuers in connection with the enrollment of qualified individuals or employees of a qualified employer, whether that enrollment is in QHPs or in non-QHPs. Section 155.210(d) further clarifies that a Navigator must not be a subsidiary of a health insurance issuer or be an association that includes members of, or lobbies on behalf of, the insurance industry.

Section 1311(i)(5) of the Affordable Care Act directs the Secretary to develop standards to ensure that information made available by Navigators is fair, accurate, and impartial.

Provisions of the Exchange regulations, at 45 CFR 155.210(c)(2), direct the Exchange to select at least two different types of entities as Navigators, one of which must be a community and consumer-focused non-profit group.

Section 1321(a) of the Affordable Care Act provides authority for the Secretary to establish standards and regulations to implement the statutory standards related to Exchanges, QHPs, and other components of title I of the Affordable Care Act.

Section 1321(c)(1) of the Affordable Care Act requires the Secretary to establish and operate Exchanges within states that either: (1) do not elect to establish an Exchange, or (2) as determined by the Secretary on or before January 1, 2013, will not have an Exchange operational by January 1, 2014. These HHS-operated Exchanges are referred to as Federally-facilitated Exchanges, and include State Partnership Exchanges.

Section 1321(d) of the Affordable Care Act states that nothing in title I of that Act shall be construed to preempt any state law that does not prevent the application of the provisions of the title. Title I of the Affordable Care Act includes all provisions related to Exchanges, including the Navigator provisions.

Provisions of the Exchange regulations, at 45 CFR 155.205(d), direct Exchanges to have a consumer assistance function that meets the accessibility standards set forth in § 155.205(c). This consumer assistance function includes the Navigator program at section 1311(i) of the Affordable Care Act and 45 CFR 155.210, but is not limited to the Navigator program.

45 CFR 155.205(e) directs Exchanges to conduct outreach and education activities that also meet the accessibility standards in § 155.205(c), and to educate consumers about the Exchange and insurance affordability programs to encourage participation. The accessibility standards for § 155.205(d) and (e), as detailed in § 155.205(c), include a requirement that applicants and enrollees be provided information in plain language and in a manner that is accessible and timely for persons with disabilities and individuals with limited English proficiency. Additionally, a notice of proposed rulemaking published on January 22, 2013 would amend § 155.205(d) [2] to require any individual providing consumer assistance under § 155.205(d) to be trained regarding QHP options, insurance affordability programs, eligibility, and benefits rules and regulations governing all insurance affordability programs operated in the state, as implemented in the state, prior to providing consumer assistance. Once finalized, that rule will apply to and require such training for non-Navigator assistance personnel.

HHS has also published a proposed a rule (78 FR 4594) that would create a new section 45 CFR § 155.225, proposing to require each Exchange to certify staff and volunteers of Exchange-designated organizations and organizations designated by State Medicaid and Children's Health Insurance Program agencies to serve as certified application counselors in the Exchange.

C. Overview of Proposed Rule

First, this proposed regulation would amend § 155.210(c)(1)(iii) to clarify that any Navigator licensing, certification, or other standards prescribed by the state or Exchange must not prevent the application of the provisions of title I of the Affordable Care Act. The proposed rule would also amend § 155.210(d) to clarify that a Navigator cannot be an issuer of, or a subsidiary of an issuer of, stop loss insurance, and cannot receive any consideration, directly or indirectly, from an issuer of stop loss insurance in connection with the enrollment of any individuals or employees in a QHP or a non-QHP. These proposed amendments to § 155.210 would be applicable to Navigators in all Exchanges, including Federally-facilitated Exchanges, State Partnership Exchanges, and State-based Exchanges.

Second, this proposed rule would add a new provision at 45 CFR 155.215 that would establish conflict-of-interest, training, and accessibility standards applicable to Navigators and non-Navigator assistance personnel in Federally-facilitated Exchanges, including State Partnership Exchanges. We also propose that these standards would apply to non-Navigator assistance programs and personnel in State-based Exchanges that are funded through federal section 1311(a) Exchange Establishment grants.

Proposed section 155.215(a) provides details on the set of conflict-of-interest standards applicable to these Navigators and non-Navigator personnel. Proposed § 155.215(a)(2)(i) would also establish that the non-Navigator assistance personnel described above must comply with the same set of conflict-of-interest prohibitions that apply to Navigators under § 155.210(d). Section 155.215(b) proposes standards related to training, certification, and recertification for these Navigators and non-Navigator personnel. These standards include details about the requirement to be certified, to register and receive training, the content required for training, and the requirement to receive a passing score on all HHS-approved certification examinations after training. Proposed § 155.215(c) and (d) would establish standards for these Navigators and non-Navigator personnel to ensure meaningful access to their services by individuals with limited English proficiency and people with disabilities. The standards proposed at 155.215(c) and (d) should be read together with all other applicable standards issued by the Secretary related to ensuring meaningful access by individuals with limited English proficiency and people with disabilities.

State-based Exchanges would not be required to use the standards proposed in § 155.215 for their Navigators, or for non-Navigator assistance programs not funded through section 1311(a) Exchange Establishment grants. However, we believe that State-based Exchanges may find the federal standards to be useful models, and could draw upon them as they develop and disseminate conflict-of-interest and training standards for Navigators pursuant to § 155.210(b), or when establishing standards for any non-Navigator assistance program that is established by the State-based Exchange that is not funded by federal 1311(a) Exchange Establishment grants.

In addition, while the conflict-of-interest, training and meaningful access standards that are now being proposed would apply to the Navigators and non-Navigator assistance personnel described above, we have not proposed that the standards would also apply to certified application counselors. Certified application counselors have been proposed as an additional source of consumer assistance, required in every Exchange, in a separate proposed rule (78 FR 4594), but that rule has not yet been finalized. We are, however, requesting public comments regarding whether all or some of the standards being proposed for Navigators and non-Navigator assistance personnel in this proposed regulation should also apply to certified application counselors in the event that every Exchange is required to establish a certified application counselor program after publication of a final rule.

II. Provisions of the Proposed Rule

A. Navigator Program Standards (Proposed Amendments to § 155.210)

The proposed rule contains two amendments to specific provisions of the existing Navigator regulation, § 155.210. These proposed amendments would apply to Navigators in all Exchanges, including Federally-facilitated Exchanges, State Partnership Exchanges and State-based Exchanges.

1. Entities and Individuals Eligible to be a Navigator (Proposed Amendment to § 155.210(c)(1)(iii))

Section 155.210(c)(1)(iii), implementing section 1311(i)(4) of the Affordable Care Act, currently directs that, to receive a Navigator grant, an entity or individual must ''meet any licensing, certification or other standards prescribed by the state or Exchange, if applicable.'' Section 1321(d) of the Affordable Care Act provides that state laws that do not prevent the application of the provisions of title I of the Affordable Care Act are not preempted.

The proposed rule would clarify that any Navigator licensing, certification, or other standards prescribed by the state or Exchange should not prevent the application of the provisions of title I of the Affordable Care Act. Thus, for example, as HHS has previously advised (see 77 FR 18310 at 18331–32), a requirement by a state or an Exchange that Navigators be agents and brokers or obtain errors and omissions coverage would violate the requirement at § 155.210(c)(2) that at least two types of entities must serve as Navigators, because it would mean that only agents

[2] *See* Notice of Proposed Rulemaking on Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes for Medicaid and Exchange Eligibility Appeals and Other Provisions Related to Eligibility and Enrollment for Exchanges, Medicaid and CHIP, and Medicaid Premiums and Cost Sharing, 78 FR 4594, 4710 (Jan. 22, 2013).

or brokers could be Navigators. In addition, holding an agent or broker license is neither necessary, nor by itself sufficient, to perform the duties of a Navigator, as these licenses generally do not address areas in which Navigators need expertise, including the public coverage options that would be available to some consumers. Similarly, if a State or Exchange required all Navigators to hold a producer license, or if a producer license was required to carry out any of the required Navigator duties, this would also conflict with § 155.210(c)(2), because in that event, all Navigators in the Exchange would be licensed agents or brokers, as defined in § 155.20.

Therefore, we propose to amend § 155.210(c)(1)(iii) to clarify, consistent with Affordable Care Act section 1321(d), that to receive a Navigator grant, an entity or individual must meet any licensing, certification or other standard prescribed by the State or Exchange, if applicable, as long as such standards do not prevent the application of the provisions of title I of the Affordable Care Act. We solicit public public comments on this proposed amendment.

2. Prohibition on Navigator Conduct (Proposed Amendment to § 155.210(d))

Under § 155.210(d), a Navigator may not be a health insurance issuer; be a subsidiary of a health insurance issuer; be an association that includes members of, or lobbies on behalf of, the insurance industry; or receive any consideration, directly or indirectly, from any health insurance issuer in connection with the enrollment of any individuals or employees in a QHP or non-QHP. We propose to amend section 155.210(d) to further clarify that a Navigator must also not be an issuer of stop loss insurance, or a subsidiary of an issuer of stop loss insurance, and must not receive any consideration, directly or indirectly, from any issuer of stop loss insurance in connection with the enrollment of individuals or employers in a QHP or non-QHP.[3]

Section 1311(i)(3)(B) of the Affordable Care Act directs that a Navigator must distribute fair and impartial information concerning enrollment in QHPs. Section 1311(i)(5) of the Affordable Care Act further directs that the Secretary shall establish standards to ensure that information made available by Navigators is fair, accurate, and impartial. In addition, section 1311(i)(4) directs the Secretary to establish standards to avoid conflicts of interest by Navigators. Existing regulations at 45 CFR 155.210(c)(1)(iv) and (e)(2) also direct that Navigators must not have a conflict of interest during their term as a Navigator, and must provide information and services in a fair, accurate, and impartial manner. Taken together, these requirements indicate that a Navigator should not have a conflict of interest when presenting information or providing the range of coverage choices to individuals or small employers who receive the Navigator's assistance. Similarly, the Navigator must not have a personal interest in the coverage choices made by individuals or employers who receive the Navigator's assistance. More specifically, with respect to the assistance offered by a Navigator to a small employer, a Navigator should not have a personal interest in whether a small employer chooses to self-insure its employees, or chooses to enroll in fully-insured coverage inside or outside the Exchange.

We believe that an issuer of stop loss insurance, a subsidiary of an issuer of stop loss insurance, or an individual or entity receiving consideration from any issuer of stop loss insurance in connection with enrollment in a QHP or non-QHP, would have conflicts of interest prohibited by § 155.210(c)(1)(iv) and such conflicts of interest would compromise the ability of a Navigator to provide information and services in a fair, accurate, and impartial manner as required by § 155.210(e)(2).

Navigators with a financial relationship with an issuer of stop loss insurance raise the same kinds of concerns that would be present for a Navigator with a relationship with a health insurance issuer (or an entity receiving consideration from a health insurance issuer). Such Navigators could have a financial incentive to encourage small employers towards self-funding and might not present all coverage options, including insured options, to small employers in a fair, accurate, and impartial manner. In addition, such conflicts of interest might interfere with a Navigator's duty to ''facilitate selection of a QHP,'' as required by § 155.210(e)(3).

The proposed amendments would help ensure that Navigators provide any small employers that request help from a Navigator with information and services in a fair, accurate, and impartial manner, and that such information facilitate small employers' selection of QHPs in Small Business Health Options (SHOP) Exchanges, if they choose to enroll in such coverage. We solicit public comments on this proposal.

B. Standards Applicable to Navigators and Non-Navigator Assistance Personnel Carrying Out Consumer Assistance Functions Under §§ 155.205(d) and (e) and 155.210 in a Federally-Facilitated Exchange and to Non-Navigator Assistance Personnel Funded Through an Exchange Establishment Grant (Proposed § 155.215)

1. Conflict-of-Interest Standards (Proposed § 155.215(a))

The proposed regulation proposes conflict-of-interest standards that are substantially similar for both Navigators and non-Navigator assistance personnel. These proposed conflict-of-interest standards would apply to all Navigators and non-Navigator assistance personnel in a Federally-facilitated Exchange (including a State Partnership Exchange), and to federally-funded non-Navigator assistance personnel in a State-based Exchange.

The standards applicable to Navigators interpret the requirements at section 1311(i)(4) of the Affordable Care Act and 45 CFR 155.210(c)(1)(iv) and (d). In addition, these standards would help ensure that Navigators provide information in a fair, accurate, and impartial manner, pursuant to Affordable Care Act section 1311(i)(5) and 45 CFR 155.210(e)(2). These standards also follow from 45 CFR 155.210(b), which specifies that Exchanges establish a set of conflict-of-interest standards applicable to Navigators in the Exchange.

We also believe that non-Navigator assistance personnel who carry out consumer outreach, assistance, and education in Federally-facilitated Exchanges, including State Partnership Exchanges, and non-Navigator assistance personnel in State-based Exchanges that are funded through Exchange Establishment grants should be subject to conflict-of-interest standards. To be helpful to the public, we believe that services provided under § 155.205(d) and (e) should be carried out in a fair, impartial, and unbiased manner. Applying conflict-of-interest standards to these non-Navigator assistance personnel will therefore ensure that they provide services consistent with this interpretation of § 155.205,and will minimize confusion in the marketplace. We solicit public comments on applying the same conflict-of-interest standards to both

[3] HHS, jointly with the Departments of Labor and the Treasury, issued a Request for Information Regarding Stop Loss Insurance on May 1, 2012. *See* 77 FR 25788. In that Request for Information, we explained that stop loss insurance is designed to protect against health insurance claims that are catastrophic or unpredictable in nature, and that it provides coverage to self-insured group health plans once a certain level of risk has been absorbed by the plan.

Navigators and non-Navigator assistance personnel.

State-based Exchanges would not be required to adopt the conflict-of-interest standards proposed in § 155.215(a) for their Navigators or for their non-Navigator assistance personnel that are not funded through 1311(a) Exchange Establishment grants. However, State-based Exchanges may wish to consider using the standards proposed in § 155.215 as models when developing their own standards.

a. Conflict-of-Interest Standards for Navigators (Proposed § 155.215(a)(1))

Section 1311(i)(4) of the Affordable Care Act directs the Secretary to establish standards for Navigators, including provisions to avoid conflicts of interest. Section 155.210(b)(1) directs all Exchanges to develop and publicly disseminate conflict-of-interest standards for Navigators. The conflict-of-interest standards proposed in § 155.215(a)(1) are intended to apply to all Navigators in Federally-facilitated Exchanges, including State Partnership Exchanges.

Section 155.210(c)(1)(iv) prohibits Navigators from having conflicts of interest during their terms as Navigators. In this context, we have explained that having a conflict of interest means having a private or personal interest sufficient to influence, or appear to influence, the objective exercise of a Navigator's official duties (77 FR 18330–18331). In addition, § 155.210(d) directs that a Navigator must not have certain relationships with insurance issuers or the insurance industry. Because any individual or entity with the conflicts of interest listed at § 155.210(d) would be barred from participating as a Navigator, the first proposed conflict-of-interest standard, as set forth in proposed § 155.215(a)(1)(i), would require that a Navigator entity, including a Navigator grant applicant, submit to the Exchange a written attestation that the Navigator and its staff do not have any of these prohibited conflicts of interest. This disclosure to the Exchange will help to ensure that Navigators comply with the prohibitions on Navigator conduct set forth in § 155.210(d), and that individuals and entities who are ineligible under § 155.210(d) do not apply to the Exchange for grants to serve as Navigators. We solicit public comments on the proposal to require Navigators to submit an attestation regarding eligibility.

Proposed § 155.215(a)(1)(ii) would direct that all Navigator entities submit to the Exchange a written plan to remain free of conflicts of interest during their term as a Navigator. This plan should ensure that the Navigator grantee, and all those individuals who serve as Navigators under the direction of the Navigator grantee, would fully comply with the prohibitions in § 155.210(d), and all other conflict-of-interest requirements, as described below, throughout the term of a Navigator grant. This would be particularly important for those Navigator entities that may have a changing workforce, and might thus utilize new or different staff or employees during the term of a Navigator grant. We solicit public comments on the proposed requirement to submit a written plan to remain free of conflicts of interest, including comments on the form of and content for the plan.

Proposed § 155.215(a)(1)(iii) would direct that all Navigators, both individual Navigators and Navigator entities, and their staff, provide information to consumers about the full range of QHP options and insurance affordability programs such as premium tax credits and cost sharing reductions and Medicaid and CHIP, for which they are eligible. This proposed requirement would help ensure that consumers receive all of the information they need to make an informed enrollment decision, and that the information they receive is fair, as required by § 155.210(e)(2).

Lastly, the proposed conflict-of-interest standards for Navigators include the requirement at proposed § 155.215(a)(1)(iv) that certain conflicts of interest, while not a bar to serving as a Navigator, should be disclosed to the Exchange and to each consumer receiving application assistance (which includes pre-enrollment and post-enrollment services, but does not include outreach and education assistance), both by the Navigator individual and the entity. In developing the conflict-of-interest standards in the proposed rule, we have been mindful that every Navigator must ''provide information and services in a fair, accurate and impartial manner'' under § 155.210(e)(2). We have also been mindful that each Exchange must develop standards ''designed to prevent, minimize and mitigate any conflicts of interest, financial or otherwise, that may exist for an entity or individuals to be awarded a Navigator grant and to ensure that all entities and individuals carrying out Navigator functions have appropriate integrity,'' § 155.210(b)(1). The requirement that an Exchange develop standards to minimize and mitigate conflicts of interests suggests that some conflicts of interest would not be absolute bars to service as a Navigator, provided that the conflict of interest would not ultimately prevent the entity or individual from providing information and services in a fair, accurate, and impartial manner. Striking this balance will allow for a robust pool of Navigators, without sacrificing the need to ensure that all Navigators have the integrity, fairness, and impartiality to carry out their duties appropriately.

Under the proposed rule, in order to mitigate conflicts of interest, there are three types of information that Navigators should disclose to the Exchange and to their consumers. First, Navigator and all Navigator staff members would be required to disclose to the Exchange and to each consumer who receives application assistance from the Navigator entity or individual, any lines of insurance business, other than health insurance or stop loss insurance, which the Navigator intends to sell while serving as a Navigator. Since Navigators must not sell health insurance and as we also propose, must not sell stop loss insurance, the proposed requirement that Navigators disclose ''any lines of insurance business'' is not intended to apply to the sale of health insurance or stop loss insurance, since these are not conflicts of interest that could be mitigated through disclosure (see § 155.210(d)).

In addition, the proposed rule would require disclosure of two other types of indirect financial conflicts of interest. Navigators and their staff members would be required to disclose to the Exchange and each consumer receiving application assistance, any existing and former employment relationships they have had within the last five years with any issuer of health insurance or stop loss insurance, or subsidiaries of such issuers. It is is intended that any existing employment relationships disclosed would be non-prohibited relationships, because receipt of any consideration directly or indirectly from any health insurance issuer or issuer of stop loss insurance in connection with the enrollment of any individuals or employees in a QHP or a non-QHP would already be prohibited by § 155.210(d)(4). They must also disclose any existing employment relationships between any health insurance issuer or stop-loss insurance issuer, or subsidiary of such issuers, and the individual's spouse or domestic partner. Navigators and their staff members would also be required to disclose to the Exchange and to each consumer receiving application assistance any existing or anticipated financial, business, or contractual relationships with one or more issuers of health insurance or stop loss insurance or subsidiaries of such

issuers. These types of conflict-of-interest relationships with issuers of health insurance or stop loss insurance should be disclosed because these relationships may confer benefits or indirect financial gain that would compromise a Navigator's objectivity. We solicit public comments on the proposed requirement to disclose certain types of potential financial conflicts of interest.

Under existing regulations, a Navigator must not act on behalf of health insurance issuers, either as agents or under appointment, since this would violate the prohibition on conflicts of interest in § 155.210(d)(1) through (d)(3) and the prohibition at § 155.210(d)(4) on receiving compensation from issuers in connection with enrollment. However, we note that agents and brokers have traditionally assisted consumers in obtaining health insurance. We anticipate that agents and brokers will continue to be an important source of assistance for many consumers seeking access to health insurance coverage through an Exchange, including those who own and/or are employed by small businesses. The proposed conflict-of-interest standards for Navigators would permit agents and brokers to serve as Navigators in an Exchange operated by HHS, provided that the agent or broker can satisfy the standards that will apply to all Navigators in the Exchange. For example, as stated above, all Navigators, including agents and brokers serving as Navigators, are prohibited from receiving consideration, directly or indirectly, from any health insurance issuer in connection with the enrollment of consumers into QHPs or non-QHPs (§ 155.210(d)(4)), and we interpret that provision to apply to the receipt of trailer commissions. Under the proposed amendments to § 155.210(d), the same prohibition would apply to agents or brokers receiving consideration from stop loss insurance issuers. Agents and brokers who sell other lines of insurance would not be prohibited from receiving consideration from the sale of those other lines of insurance while serving as Navigators, provided they complied with the disclosure requirement.

If an entity or organization is awarded a grant to be a Navigator, the entity as a whole is considered to be a Navigator. Therefore, the prohibition on receipt of compensation from certain insurance issuers in connection with the enrollment of consumers into QHPs or non-QHPs, would apply to the entire organization and its entire staff. While a Navigator could retain staff members who serve as agents and brokers, those staff members—and the organization itself—could not receive compensation from health insurance or stop loss insurance issuers for enrolling individuals or employees in QHPs or health insurance plans outside of the Exchange. Such staff members, however, could continue to be compensated for selling other insurance products (for example, auto, life, and homeowners' policies).

We solicit public comments on the proposed conflict-of-interest standards applicable to Navigators.

b. Conflict-of-Interest Standards for Non-Navigator Assistance Personnel Carrying Out Consumer Assistance Functions Under § 155.205(d) and (e) (Proposed § 155.215(a)(2))

Proposed § 155.215(a)(2) would establish a set of parallel conflict-of-interest standards that would apply in Federally-facilitated Exchanges (including State Partnership Exchanges) to non-Navigator assistance personnel carrying out consumer assistance functions under 155.205(d) and (e), and to federally-funded non-Navigator assistance personnel in a State-Based Exchange. As discussed above, we believe the same conflict-of-interest considerations that apply to Navigators should also apply to these non-Navigator assistance personnel. With respect to the requirement to submit a mitigation plan under proposed § 155.215(a)(2)(iii), consistent with the requirement that only a Navigator entity (not individual staff) would be required to submit the plan, the mitigation plan would only be required on an individual basis if the individual is not working for an entity serving as non-Navigator assistance personnel.

In addition, the proposed rule would direct that these non-Navigator assistance personnel adhere to and comply with the same restrictions on participation and prohibitions on conduct that apply to Navigators under § 155.210(d). Therefore, like Navigators, individuals and entities performing non-Navigator assistance functions under § 155.205(d) and (e) must not have any of the disqualifying conflicts of interest arising from being an issuer of health insurance or stop loss insurance, a subsidiary of such an issuer, or an association with members that are issuers or that lobbies for health insurance or stop loss issuers, or from receiving compensation from an issuer of health insurance or stop loss insurance in connection with enrollment in QHPs or non-QHPs. We solicit public comments on the application of these proposed standards to non-Navigator assistance personnel.

2. Training Standards for Navigators and Non-Navigator Assistance Personnel Carrying Out Consumer Assistance Functions Under §§ 155.205(d) and (e) and 155.210 (Proposed § 155.215(b))

Existing regulations at 45 CFR 155.210(b)(2) direct Exchanges to develop and disseminate a set of training standards, to be met by all entities and individuals carrying out Navigator functions. Under § 155.210(b)(2), the training standards developed by the Exchange must ensure Navigator expertise in eligibility and enrollment rules and procedures, the range of QHP options and insurance affordability programs, the needs of underserved and vulnerable populations, and privacy and security requirements applicable to personally identifiable information. In addition, to receive a Navigator grant, § 155.210(c)(1)(iii) directs that an entity or individual must meet any licensing, certification, or other standards prescribed by the state or Exchange, if applicable.

In addition, in the proposed rule relating to Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes for Medicaid and Exchange Eligibility Appeals and Other Provisions Related to Eligibility and Enrollment for Exchanges, Medicaid and CHIP, and Medicaid Premiums and Cost Sharing, published on January 22, 2013 (78 FR 4594, 4710), we proposed an amendment to § 155.205(d) that would require any individual providing consumer assistance under that section, including Navigators, to ''be trained regarding QHP options, insurance affordability programs, eligibility, and benefits rules and regulations governing all insurance affordability programs operated in the state, as implemented in the state, prior to providing such assistance.''

Consistent with the existing requirements in § 155.210(b)(2) and § 155.210(c)(1)(iii) and the proposed requirements at 78 FR 4710, we now propose a specific set of training standards that would require up to 30 hours of training, including standards for certification and recertification, for all Navigators and non-Navigator assistance personnel in Federally-facilitated Exchanges, including State Partnership Exchanges, and all federally funded non-Navigator assistance personnel in State-based Exchanges, to ensure that these entities and individuals can satisfy the duties and obligations of serving as Navigators or non-Navigator assistance personnel. These proposed standards would be

applicable to all Navigators and non-Navigator assistance personnel in Federally-facilitated Exchanges, including State Partnership Exchanges, and to all federally funded non-Navigator assistance personnel in State-based Exchanges, and can be used by State-based Exchanges at their option for their Navigator personnel and non-federally funded non-Navigator assistance personnel.

a. Certification and Recertification Standards (Proposed § 155.215(b)(1))

Section 1311(i)(4) of the Affordable Care Act directs the Secretary to establish standards for Navigators, including provisions to ensure that any private or public entity that is selected as a Navigator is qualified, and licensed if appropriate, to engage in Navigator activities and to avoid conflicts of interest. Under existing regulations at 45 CFR 155.210(c)(1)(iii), Navigators must meet any ''licensing, certification or other standards prescribed by the state or Exchange, if applicable.'' In addition, we have previously proposed to amend § 155.205(d) to require that any individual providing consumer assistance under § 155.205(d) must be trained regarding QHP options, insurance affordability programs, eligibility, and benefits rules and regulations governing all insurance affordability programs operated in the state, as implemented in the state, prior to providing such assistance (78 FR 4594).

We now propose in § 155.215(b)(1) that all Navigators and non-Navigator assistance personnel in a Federally-facilitated Exchange or State Partnership Exchange, and federally-funded non-Navigator assistance personnel in a State-Based Exchange, register with the Exchange and be certified by the Exchange, and prior to certification, complete an HHS-approved training before carrying out any consumer assistance functions in the Exchange. We propose in § 155.215(b)(2) the topics about which such Navigators and non-Navigator assistance personnel would receive training prior to certification. The proposed rule would also direct that individuals and staff of Navigator entities and non-Navigator assistance entities receive a passing score on all HHS-approved examinations in order to serve as Navigators or non-Navigator assistance personnel in a Federally-facilitated Exchange, a State Partnership Exchange, or as federally-funded non-Navigator assistance personnel in a State-based Exchange.

The proposed recertification requirement for Navigators and non-Navigator assistance personnel would ensure that they remain appropriately trained to adequately serve consumers. The rule also proposes that Navigators and non-Navigator assistance personnel should obtain continuing education and be certified and/or recertified on at least an annual basis.

We also propose that these certification requirements would specifically direct that all Navigators and non-Navigator assistance personnel be prepared to serve both the individual Exchange and SHOP in a Federally-facilitated Exchange. Section 1311(i)(2)(A) of the Affordable Care Act directs that, to be eligible to receive a Navigator grant, an entity must demonstrate that it has existing relationships, or could readily establish relationships, with employers and employees. In addition, section 1311(i)(2)(B) directs that the types of entities that may be eligible for a Navigator grant include resource partners of the Small Business Administration. We infer from these standards that Navigators must be prepared to serve the needs of small businesses, and therefore will need to be prepared to serve the needs of both the individual Exchange and SHOP. We also believe that non-Navigator assistance personnel who carry out consumer outreach, assistance, and education in the Exchange and are paid for by Federal funding should be prepared to serve the needs of both the individual Exchange and SHOP. In order to be truly helpful and useful to the public, we believe that services provided under § 155.205(d) and (e) should be available to all consumers, including small businesses. Directing non-Navigator assistance personnel in Federally-facilitated Exchanges, including State Partnership Exchanges, and federally funded non-Navigator assistance personnel in State-based Exchanges to provide assistance to all consumers will ensure that they provide services consistent with this interpretation of § 155.205.

Each Navigator and non-Navigator assistance personnel should have the ability to help any individual who presents him or herself for assistance. However, there may be some instances where a Navigator, or non-Navigator assistance personnel, does not have the immediate capacity to help an individual. In such cases, the Navigator or non-Navigator assistance personnel should be capable of providing assistance in a timely manner but should also refer consumers seeking assistance to other Exchange resources, such as the toll-free Exchange Call Center, or to another Navigator or non-Navigator assistance personnel in the same Exchange who might have better capacity to serve that individual more effectively.

We solicit public comments on these proposed training and certification standards, including the proposed recertification standards.

b. Training Module Content Standards (Proposed § 155.215(b)(2))

Each entity that serves as a Navigator, and each individual that will carry out Navigator functions under the terms of a Navigator grant in a Federally-facilitated Exchange or State Partnership Exchange, must receive training to perform all of the duties of a Navigator. Although different Navigators may perform these duties at different levels of effort or focus, every Navigator must be trained to perform all of the listed duties in section 1311(i)(3) of the Affordable Care Act and in § 155.210(e). Therefore, in order to carry out a Navigator's duties to maintain expertise in eligibility and facilitate selection of QHPs, all Navigators will receive training so that they are equipped with the necessary information to help consumers apply for coverage through the Exchange, which will ultimately result in an eligibility determination for enrollment in a QHP and/or an insurance affordability program. Non-Navigator assistance personnel must receive comparable training with respect to their specific responsibilities. In addition, Navigators and non-Navigator assistance personnel must receive training on the privacy and security requirements for the protection of personally identifiable information, including relevant state laws.

In addition to training designed to help Navigators and non-Navigator assistance personnel build expertise in eligibility and facilitating selection of QHPs, training for Navigators and non-Navigator assistance personnel should prepare them to educate consumers about the advanced payments of the premium tax credit and cost-sharing reductions and help them submit the appropriate information to receive an eligibility determination for insurance affordability programs, including advanced payments of the premium tax credits and cost-sharing reductions. In addition, Navigators should be trained so that they will be prepared to fulfill the duty at § 155.210(e)(2) to ''provide information and services in a fair, accurate and impartial manner,'' including the requirement that ''such information acknowledge other health programs,'' including Medicaid and CHIP. Therefore, § 155.215(b)(2) proposes a set of standards for the content of the training module for

Navigators and non-Navigator assistance personnel in a Federally-facilitated Exchange or State Partnership Exchange, and for federally funded non-Navigator assistance personnel in a State-based Exchange, to ensure that they would be knowledgeable in these areas, and fully prepared to assist consumers.

The Exchange regulations, at 45 CFR 155.260(a), establish privacy and security standards for Exchanges, and § 155.260(b) provides that Exchanges must require Navigators and other non-Exchange entities to abide by the same or more stringent privacy and security standards as a condition of contract or agreement with such entities. Consistent with these requirements, we propose that the training for Navigators and non-Navigator assistance personnel must include training designed to ensure that they safeguard consumers' sensitive personal information including but not limited to health information, income and tax information, and Social Security number.

Subsections 155.205(d) and (e) direct Exchanges to conduct consumer assistance, outreach, and education activities, including Navigator programs, in a way that meets the standards set forth at § 155.205(c). Section 155.205(c), in turn, directs Exchanges to provide information to applicants and enrollees in plain language and in a manner that is accessible and timely to individuals living with disabilities and individuals who are limited English proficient (LEP). Additionally, § 155.210(e)(5) directs Navigators to provide information in a manner that is culturally and linguistically appropriate to the needs of the population served by the Exchange, including individuals with limited English proficiency, and to ensure accessibility and usability of Navigator tools and functions for individuals with disabilities. We interpret the foregoing provisions to require all entities and individuals carrying out activities authorized by §§ 155.205(d) and (e) and155.210, including Navigators and non-Navigator assistance personnel, to be knowledgeable about the special needs of populations with limited English proficiency and people with a full range of disabilities, and how best to communicate with and assist these consumers. The rule therefore proposes that the training for Navigators and non-Navigator assistance personnel would include training designed to ensure that they will be equipped to provide culturally and linguistically appropriate services and ensure physical and other accessibility for people with disabilities. We solicit public comments on the proposed requirement to receive training regarding culturally and linguistically appropriate services as well as accessibility for people with disabilities.

3. Providing Culturally and Linguistically Appropriate Services (CLAS Standards) (Proposed § 155.215(c))

Proposed § 155.215(c) and (d) detail standards for the use and provision of culturally and linguistically appropriate tools and services as well as requirements to ensure access by individuals with disabilities who seek assistance from Navigators and non-Navigator assistance personnel in Federally-facilitated Exchanges, including State Partnership Exchanges, and from federally-funded non-Navigator assistance personnel in a State-based Exchange.

Section 1311(i)(3)(E) of the Affordable Care Act directs that Navigator entities have a duty to provide information in a manner that is culturally and linguistically appropriate to the needs of the population being served by the Exchange or Exchanges. According to the regulation implementing this provision, Navigators must ''provide information in a manner that is culturally and linguistically appropriate to the needs of the population being served by the Exchange, including individuals with limited English proficiency'' (§ 155.210(e)(5)). Additionally, all non-Navigator assistance personnel must meet the accessibility standards set forth at § 155.205(c).

Independent of these obligations, certain Federal civil rights laws, such as Title VI of the Civil Rights Act of 1964 and Section 504 of the Rehabilitation Act of 1973, also apply to Navigators in Federally-facilitated and State Partnership Exchanges. These laws would also apply to non-Navigator assistance programs in State-based and State Partnership Exchanges to the extent such programs receive federal financial assistance. These federal civil rights laws impose nondiscrimination obligations with respect to persons with disabilities and that address the communications needs of persons who have limited English proficiency (LEP).

While the proposed training module content standards discussed earlier in this preamble include a requirement that training include providing culturally and linguistically appropriate services, this proposed rule also provides more specific standards for ensuring meaningful access. These proposed standards should be read together with all other applicable standards issued by the Secretary related to ensuring meaningful access by individuals with limited English proficiency.

The specific standards proposed in § 155.215(c) include that Navigators and non-Navigator assistance personnel develop, maintain, and regularly update general knowledge about the racial, ethnic, and cultural groups in their service area, including the primary languages spoken, and continue to use this information. The proposed requirements would also include that such entities and individuals provide consumers with information and assistance in the consumer's preferred language, at no cost to the consumer, which would include oral interpretation of non-English languages and the translation of written documents in non-English languages when necessary to ensure meaningful access. We also propose that use of a consumer's family or friends as interpreters can satisfy the requirement to provide linguistically appropriate services only when requested by the consumer as the preferred alternative to an offer of other interpretive services. We anticipate that most Navigators and non-Navigator assistance personnel would use readily available telephonic interpretation services and other effective low-cost services in order to meet the requirement to provide language access to the consumers they serve, so that it will not be costly or onerous.

In addition, § 155.215(c)(4) of the proposed rule would require that non-Navigator assistance personnel provide limited-English-proficiency consumers with oral and written notices informing them of their right to receive language assistance services and how to obtain such services. This requirement could be satisfied using methods outlined in existing § 155.205(c)(2), which allows for the use of taglines in non-English languages placed on documents or Web sites to indicate the availability of language services.

Section 155.215(c)(6) of the proposed rule would also direct Navigator and non-Navigator assistance personnel entities to implement strategies to recruit and promote a staff that is representative of the demographic characteristics, including primary languages spoken, of the communities in their service area.

4. Standards Ensuring Access by Persons With Disabilities (Proposed § 155.215(d))

Section 155.210(e)(5) directs that an entity serving as a Navigator has a duty to ''ensure accessibility and usability of

Navigator tools and functions for individuals with disabilities in accordance with the Americans with Disabilities Act and Section 504 of the Rehabilitation Act.'' Similarly, § 155.205(c) requires that persons providing consumer assistance pursuant to § 155.205(d) and (e) provide individuals living with disabilities with information that is accessible at no cost to the individual, in accordance with the Americans with Disabilities Act and section 504 of the Rehabilitation Act.

Additionally, independent of these obligations, certain Federal civil rights laws, such as Title VI of the Civil Rights Act of 1964 and Section 504 of the Rehabilitation Act of 1973, also apply to Navigators in Federally-facilitated and State Partnership Exchanges. These laws would also apply to non-Navigator assistance programs in State-based and State Partnership Exchanges to the extent such programs receive federal financial assistance. These federal civil rights laws impose nondiscrimination obligations with respect to persons with disabilities and that address the communications needs of persons who have limited English proficiency (LEP).

In accordance with these requirements, § 155.215(d)(2) of the proposed rule would direct that auxiliary aids and services for individuals with disabilities be provided at no cost where necessary for effective communication. The proposal specifies that the use of a consumer's family or friends as interpreters can satisfy the requirement to provide auxiliary aids and services only when requested by the consumer as the preferred alternative to an offer of other auxiliary aids and services. In addition, proposed section 155.215(d)(3) would require Navigators and non-Navigator assistance personnel in a Federally-facilitated Exchange or State Partnership Exchange, and federally-funded non-Navigator assistance personnel in a State-based Exchange to provide assistance to consumers in a location and in a manner that is physically and otherwise accessible to individuals with disabilities. Proposed section 155.215(d)(1) would direct Navigators and non-Navigator assistance personnel to ensure that any consumer education materials, Web sites, or other tools utilized for consumer assistance purposes are accessible to people with disabilities.

Section 155.215(d)(4) of the proposed rule would also require that legally authorized representatives be permitted to assist individuals with disabilities to make informed decisions. Finally, proposed § 155.215(d)(5) would direct that individuals carrying out Navigator and non-Navigator assistance functions have the ability to refer people with disabilities to local, state, and federal long-term services and supports programs when appropriate. We seek comment on this requirement.

These proposed standards should be read together with all other applicable standards issued by the Secretary related to ensuring meaningful access by people with disabilities.

5. Monitoring (Proposed § 155.215(e))

The proposed rule indicates that Federally-facilitated Exchanges (including State Partnership Exchanges) will monitor compliance with the standards described in § 155.215 and with the requirements described in § 155.205(d) and (e) and 155.210. To the extent possible, these Exchanges will engage in monitoring whether Navigators and non-Navigator assistance personnel comply with those standards, including, for example, reviewing reports filed by Navigators and reviewing the attestations and conflict-of-interest plans required to be submitted to the Exchange as proposed in § 155.215(a)(1)(i) through (ii) and (a)(2)(ii) through (iii) of the proposed regulation; conducting discussions with states in which Navigator grantees and non-Navigator assistance personnel exercise their functions; and reviewing casework and complaints filed with the Exchange or a relevant state. We solicit comments on how monitoring for federally-funded non-Navigator assistance personnel in State-based Exchanges should be conducted.

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 (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.

This proposed rule would establish conflict-of-interest and training standards, including standards for certification and recertification, for Navigators and non-Navigator assistance personnel in an Exchange being operated by HHS as a Federally-facilitated Exchange or as a State Partnership Exchange pursuant to HHS authority under section 1321(c)(1) of the Affordable Care Act and for non-Navigator assistance personnel in State-based Exchanges that are funded through federal Exchange Establishment grants. The proposal requires that these Navigators and non-Navigator assistance personnel provide an attestation that they are not ineligible individuals or entities and submit a plan for mitigating conflicts of interest, register with the Exchange, receive training, be initially certified, and receive subsequent recertification with the Exchange.

Section III.A outlines information collection requirements associated with disclosure of conflicts of interest. These disclosures include an attestation regarding eligibility to be a Navigator or non-Navigator assistance personnel; a plan for mitigating conflicts of interest; a requirement to provide information to consumers about their coverage options; and a requirement to disclose other potential, non-prohibited, conflicts of interest. Section III.B outlines information collection requirements associated with registration, certification, and recertification requirements. We are soliciting public comments on each of these issues for the following sections of the proposed rule that contain information collection requirements (ICRs).

For purposes of the information collection requirements, Navigator personnel and non-Navigator assistance personnel are estimated to have a professional wage of $20 per hour.[4] Navigator and non-Navigator assistance project leads are estimated to have a professional wage of $29 per hour.[5] Navigator senior executives are estimated to have a professional wage of $48 per hour.[6] The average professional wage for Navigator personnel, projects

[4] These positions are estimated to be equivalent to a GS–9 position with the Federal government. *See http://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2012/general-schedule/gs_h.pdf.*

[5] These positions are estimated to be equivalent to a GS–12 position with the Federal government. *See http://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2012/general-schedule/gs_h.pdf.*

[6] These positions are estimated to be equivalent to a GS–15 position with the Federal government. *See http://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2012/general-schedule/gs_h.pdf.*

leads, senior executives, and non-Navigator assistance personnel and project leads is estimated to be $29.20 per hour.

At this time we are unable to estimate the number of Navigator grantees and applicants or the number of non-Navigator assistance personnel and project leads; therefore the estimates discussed below are on a per individual basis. Additionally, we are unable to estimate the number of consumers expected to receive assistance from Navigator grantees or non-Navigator assistance personnel; therefore estimates for disclosures to consumers discussed below are on a per consumer basis. We invite public comments on the number of Navigator grantees or the number of non-Navigator assistance personnel and project leads expected, as well as the number of consumers expected to receive assistance.

A. ICRs Regarding Disclosure of Conflicts of Interest (Proposed § 155.215(a))

Pursuant to proposed § 155.215(a)(1)(i) & (iv) and (a)(2)(ii) & (v), Navigator program grantees and other entities and individuals providing assistance under §§ 155.205(d) and (e) would be required to disclose conflicts of interest. This disclosure would include an attestation that an individual or entity is not an ineligible entity. Additionally, pursuant to proposed § 155.215(a)(1)(ii) and (a)(2)(iii), a plan for mitigating any conflicts of interest would also be submitted. The cost burden associated with the attestation would apply to each Navigator entity and applicant, and to each individual or entity serving as non-Navigator assistance personnel. The cost burden associated with the plan for mitigating any conflicts of interest will apply to each Navigator program grantee and to each individual or entity serving as non-Navigator assistance personnel.[7] The attestation and mitigation plan are one-time requirements.

We estimate it will take Navigator personnel, project leads, senior executives, non-Navigator assistance personnel, and non-Navigator assistance project leads 0.25 hours (15 minutes) each to prepare and provide the attestation that they are an eligible entity. With a wage of $20 per hour for Navigator and non-Navigator personnel, $29 per hour for Navigator and non-Navigator project leads, and $48 per hour for senior executives, we estimate the cost burden per Navigator personnel would be $5, per Navigator project lead would be $7.25, per Navigator senior executives would be $12, per non-Navigator assistance personnel would be $5, and per non-Navigator assistance personnel would be $7.25. The total burden per person would be 0.25 hours and $7.30 on average.

The plan for mitigating conflicts of interest would be required on a per entity basis;[8] therefore we assume for Navigator program grantees, the senior executive would be responsible for developing and providing the plan for mitigating conflicts of interest because only one plan is required per grantee. For purposes of the ICR we are assuming burden and cost estimates based on a non-Navigator assistance project lead wage of $29 per hour.

We estimate that for a Navigator program grantee it will take a senior executive up to 5 hours to prepare and provide a plan for mitigating conflicts of interest and a non-Navigator assistance project lead would also require up to 5 hours to prepare and provide a plan for mitigating conflicts of interest. With a wage of $48 per hour for senior executives and $29 per hour for non-Navigator assistance project leads, we estimate the total one-time annual cost burden for a Navigator program grantee would be $240, and for non-Navigator assistance project leads would be $145.

Pursuant to proposed § 155.215(a)(1)(iii) and (a)(2)(iv), Navigator program grantees and non-Navigator assistance personnel would be required to provide information to consumers about the full range of QHP options and insurance affordability programs for which they are eligible. We assume that the total time to provide this disclosure would be one hour per disclosure. We assume for the Navigator program grantee that the Navigator personnel would prepare the disclosure and the total burden estimated per disclosure would be 1 hour at a cost of $20. For non-Navigator assistance personnel we estimate the total burden per disclosure would be 1 hour for preparing the disclosure at a cost of $20. The total burden per disclosure would be 1 hour and $20 on average.

Pursuant to proposed § 155.215(a)(1)(iv) and (a)(2)(v), Navigator personnel, projects leads, senior executives, non-Navigator assistance personnel, and non-Navigator assistance project leads would be required to disclose the Exchange and to consumers: any lines of insurance business, not covered by the restrictions on participation and prohibitions on conduct in § 155.210(d), which they intend to sell while carrying out the consumer assistance functions; any existing and former employment relationships within the last five years with any health insurance issuers or issuers of stop loss insurance or subsidiaries of health insurance issuers or issuers of stop loss insurance; any existing employment relationships between a spouse or domestic partner and any health insurance issuers or issuers of stop loss insurance or subsidiaries of health insurance issuers or issuers of stop loss insurance; and any existing or anticipated financial, business, or contractual relationships with one or more health insurance issuers or issuers of stop loss insurance, or subsidiaries of health insurance issuers or issuers of stop loss insurance. We estimate the total time to prepare this disclosure would be 0.16 hours (10 minutes). The total cost estimated for preparing this disclosure per Navigator personnel would be $3.20, per Navigator project lead would be $4.64, per Navigator senior executive would be $7.68, per non-Navigator assistance personnel would be $3.20, and per non-Navigator assistance project lead would be $4.64. The total burden per person would be 0.16 hours and $4.67 on average.

B. ICRs Regarding Training and Certification Standards (Proposed § 155.215(b))

1. Registration Prior to Training

Pursuant to proposed § 155.215(b)(1)(ii), Navigator personnel, project leads, senior executives, non-Navigator assistance personnel, and non-Navigator assistance project leads would be required to register prior to training. We assume that it will take Navigator personnel, project leads, senior executives, non-Navigator assistance personnel, and non-Navigator assistance project leads each 0.25 hours (15 minutes) to register. With a wage of $20 per hour for Navigator and non-Navigator assistance personnel, $29 for Navigator and non-Navigator assistance project leads, and $48 for senior executives, we estimate the total cost burden for Navigator personnel would be $5, for Navigator project leads would be $7.25, for Navigator senior executives would be $12, for non-Navigator assistance personnel would be $5, and for non-Navigator assistance project leads would be $7.25. The total burden per person would be 0.25 hours and $7.30 on average.

[7] The mitigation plan is only required on an individual basis if the individual is not working for an entity serving as non-Navigator assistance personnel.

[8] An individual could be serving as an entity.

2. Certification and Recertification

Pursuant to § 155.215(b)(1), Navigator personnel, project leads, senior executives, non-Navigator assistance personnel, and non-Navigator assistance project leads would be required to complete a training program to obtain certification consisting of up to 30 hours of training including any approved certification exams. There are recordkeeping requirements associated with the certification and recertification provisions. Each person who receives training would be expected to obtain and maintain a record of certification. Pursuant to § 155.215(b)(1)(iv), Navigator personnel, project leads, senior executives, non-Navigator assistance personnel, and non-Navigator assistance project leads who intend to continue beyond their initial period of performance would be required to be recertified on an annual basis. Each person who receives recertification would be expected to obtain proof of recertification and keep it on file. It is estimated that the time burden associated with maintaining proof of certification or recertification would be 0.016 hours (1 minute); we assume proof will be maintained through electronic copies with minimal cost.

The total cost estimated for maintaining proof of certification or recertification per Navigator would be $0.32; per Navigator project lead would be $0.48; per Navigator senior executive would be $0.75; per non-Navigator assistance personnel would be $0.32, and per non-Navigator assistance project lead would be $0.48. In the initial year the requirement will be to maintain proof of initial certification; in subsequent years the requirement will be to maintain proof of recertification. Because these requirements would be the same time and cost burden we are categorizing them as one annual burden. The total annual burden estimated for maintaining proof of certification or recertification would be 0.016 hours and $0.47 on average.

TABLE 1—ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS, BY RESPONDENT

Proposed regulation section(s)	OMB control No.	Burden per response (hours)	Hourly labor cost of reporting ($) **	Total labor cost of reporting ($)	Total capital/ maintenance costs ($)
Conflict of Interest Attestation § 155.215(a)(1)(i) & (a)(2)(ii).	0938–New	0.25	29.20	7.30	0
Conflict of Interest Mitigation Plan§ 155.215(a)(1)(ii) & (a)(2)(iii) Navigator Senior Executive.	0938–New	5	48	240	0
Non-Navigator Assistance Project Lead	5	29	145	0	
Conflict of Interest Disclosure of Coverage Options § 155.215(a)(1)(iii) & (a)(2)(iv).	0938–New	1	20	20	0
Conflict of Interest Disclosure to Exchange and Consumers § 155.215(a)(1)(iv) & (a)(2)(v).	0938–New	.16	29.20	4.67	0
Training Registration § 155.215(b)(1)(ii)	0938–New	0.25	29.20	7.30	0
Certification and Recertification § 155.215(b)(1)	0938–New	0.016	29.20	0.47	0
Total				424.27	0

** The hourly cost of $29.20 in certain rows is an average of the professional wages estimated for Navigator personnel, project leads, senior executives, non-Navigator assistance personnel, and non-Navigator assistance project leads.

IV. Regulatory Impact Statement

A. Summary

HHS is publishing this proposed rule to implement the protections intended by Congress in the most economically efficient manner possible. HHS has examined the effects of this rule as required by Executive Order 13563 (76 FR 3821, January 21, 2011), Executive Order 12866 (58 FR 51735, September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), Executive Order 13132 on Federalism, and the Congressional Review Act (5 U.S.C. 804(2)).

B. Executive Orders 12866 and 13563

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). Executive Order 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866. OMB has determined that this proposed rule is a ''significant regulatory action'' under Executive Order 12866. Accordingly, OMB reviewed this proposed rule.

1. Need for Regulatory Action

This proposed regulation would establish conflict of interest, training and certification, and meaningful access standards applicable to Navigator programs in Federally-facilitated Exchanges, including State Partnership Exchanges, non-Navigator assistance programs in State Partnership Exchanges, and non-Navigator assistance programs in State-Based Exchanges that are funded through federal 1311(a) Exchange Establishment grants. The proposed rule would require that these Navigators and non-Navigator assistance personnel register with and be certified by the Exchange. In addition, the proposed rule would establish standards for Navigators and non-Navigator assistance personnel to ensure meaningful access to their services by individuals with limited English proficiency and individuals with disabilities.

The proposed rule also would amend existing regulations to clarify that Navigators must meet any licensing, certification or other standards prescribed by the State or Exchange, if applicable, so long as such standards do not prevent the application of the provisions of title I of the Affordable Care Act; add entities with relationships with issuers of stop loss insurance, including those who are compensated directly or indirectly by issuers of stop loss insurance in connection with enrollment in QHPs or non-QHPs, to the list of entities ineligible to become Navigators; and clarify that the same ineligibility criteria that apply to

Navigators providing services in any Federally-facilitated Exchange, including State Partnership Exchanges, would also apply to non-Navigator assistance personnel providing assistance in State Partnership Exchanges and federally-funded non-Navigator assistance personnel in State-based Exchanges.

2. Summary of Impacts

The proposed regulations would help ensure that Navigators in Federally-facilitated Exchanges, non-Navigator assistance personnel in State Partnership Exchanges, and federally-funded non-Navigator assistance personnel in State-based Exchanges will be fair and impartial, will be appropriately trained, and will provide services and information in a manner that is accessible to persons with limited English proficiency and persons with disabilities. The proposed rule would also ensure that Navigators meet any licensing, certification or other standards prescribed by the State or Exchange, if applicable, so long as such standards do not prevent the application of the provisions of title I of the Affordable Care Act.

Navigators and non-Navigator assistance personnel would incur costs in order to comply with the provisions of this proposed rule, which would be covered by the Navigator grants and other compensation provided by the Exchange to non-Navigator assistance personnel. HHS anticipates that the impacts of the proposed rule would not be economically significant.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires agencies that issue a regulation to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. The RFA generally defines a ''small entity'' as: (1) A proprietary firm meeting the size standards of the Small Business Administration (SBA); (2) a nonprofit organization that is not dominant in its field; or (3) a small government jurisdiction with a population of less than 50,000 (states and individuals are not included in the definition of ''small entity''). HHS uses as its measure of significant economic impact on a substantial number of small entities a change in revenues of more than 3 to 5 percent.

HHS anticipates that the proposed rule would not have a significant economic impact on a substantial number of small entities. Some of the entities that act as Navigators and non-Navigator assistance personnel may be small entities and would incur costs to comply with the provisions of this rule. It should be noted that serving as a Navigator or non-Navigator assistance personnel is voluntary, and the cost burden related to registering for accounts, verification of registration, initial online training and certification, continuing education and recertification, conflict of interest notification, and providing assistance to consumers would be covered by the Navigator grants and other compensation provided by the Exchange to non-Navigator assistance personnel. Due to lack of data, HHS is unable to estimate how many small entities would elect to serve as Navigators and non-Navigator assistance personnel. We invite public comments on this issue.

The size threshold for ''small'' business established by the SBA is currently $7 million in annual receipts for insurance agencies and brokerages.[9] As discussed earlier, we anticipate that agents and brokers will continue to be an important source of assistance for many consumers seeking access to health insurance coverage through an Exchange, including those who own and/or are employed by small businesses. The proposed conflict of interest standards for Navigators would permit agents and brokers to serve as Navigators in an Exchange operated by HHS, provided that the agent or broker can satisfy the standards that would apply to all Navigators in the Exchange. Additionally, we anticipate that agents and brokers will also play a role in educating consumers about Exchanges and insurance affordability programs, and in helping consumers receive eligibility determinations, compare plans, and enroll in coverage to the extent permitted by a given state.

In addition, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a rule may have a significant economic 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. This proposed rule would not affect small rural hospitals. Therefore, the Secretary has determined that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

D. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits before issuing any rule that includes a federal mandate that could result in expenditure in any one year by state, local, or tribal governments, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. In 2013, that threshold level is approximately $141 million.

UMRA does not address the total cost of a final rule. Rather, it focuses on certain categories of cost, mainly those ''Federal mandate'' costs resulting from—(1) imposing enforceable duties on state, local, or tribal governments, or on the private sector; or (2) increasing the stringency of conditions in, or decreasing the funding of, state, local, or tribal governments under entitlement programs.

This proposed rule does not mandate expenditures by state governments, local governments, tribal governments, or the private sector, of $141 million. The cost burden for Navigators and non-Navigator assistance personnel related to registering for accounts, verification of registration, initial online training and certification, continuing education and recertification and conflict of interest notification would be covered by the Navigator grants and other compensation provided by the Exchange to non-Navigator assistance personnel and would not exceed the UMRA threshold. As discussed previously in the preamble, state-based Exchanges and state partners in State Partnership Exchanges may use section 1311(a) Exchange Establishment grants to fund non-Navigator assistance programs. Section 1311(i)(6) prohibits Exchanges from using section 1311(a) grant funds to fund Navigator grants. Section 1311(a) grant funds, however, may be used to cover the Exchange's cost of administering the Navigator program, including, for example, the cost of Navigator training, grants management, and oversight.

E. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirement costs on state and local governments or has federalism implications.

The proposed rule would clarify that any Navigator licensing, certification, or other standards prescribed by the state or Exchange should not prevent the application of the provisions of title I of the Affordable Care Act. An entity or individual would be required to meet any licensing, certification, or other standards prescribed by the State or

[9] ''Table of Size Standards Matched To North American Industry Classification System Codes,'' effective January 7, 2013, U.S. Small Business Administration, available at *http://www.sba.gov.*

Exchange, if applicable, so long as such standards do not prevent the application of the provisions of title I of the Affordable Care Act.

Throughout the process of developing this proposed regulation, HHS has attempted to balance the states' interests and Congress' intent to provide uniform minimum protections to consumers in every state. By doing so, it is HHS's view that we have complied with the requirements of Executive Order 13132. Pursuant to the requirements set forth in section 8(a) of Executive Order 13132, and by the signatures affixed to this regulation, the Department certifies that the Centers for Medicare & Medicaid Services has complied with the requirements of Executive Order 13132 for the proposed regulation in a meaningful and timely manner.

F. Congressional Review Act

This proposed rule is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. § 801, et seq.), which specifies that before a rule can take effect, the federal agency promulgating the rule shall submit to each House of the Congress and to the Comptroller General a report containing a copy of the rule along with other specified information.

List of Subjects in 45 CFR Part 155

Administrative practice and procedure, Advertising, Brokers, Conflict of interest, Consumer protection, Grant programs-health, Grants administration, Health care, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Loan programs-health, Organization and functions (Government agencies), Medicaid, Public assistance programs, Reporting and recordkeeping requirements, Safety, State and local governments, Technical assistance, Women, and Youth.

For the reasons stated in the preamble, the Department of Health and Human Services proposes to amend 45 CFR part 155 as set forth below:

PART 155—EXCHANGE ESTABLISHMENT STANDARDS AND OTHER RELATED STANDARDS UNDER THE AFFORDABLE CARE ACT

■ 1. The authority citation for part 155 continues to read as follows:

Authority: Title I of the Affordable Care Act, sections 1301, 1302, 1303, 1304, 1311, 1312, 1313, 1321, 1322, 1331, 1334, 1402, 1411, 1412, 1413.

■ 2. Section 155.210 is amended by revising paragraphs (c)(1)(iii), (d)(1), (d)(2), and (d)(4) to read as follows:

§ 155.210 Navigator program standards.

* * * * *

(c) * * *

(1) * * *

(iii) Meet any licensing, certification or other standards prescribed by the State or Exchange, if applicable, so long as such standards do not prevent the application of the provisions of title I of the Affordable Care Act;

* * * * *

(d) * * *

(1) Be a health insurance issuer or issuer of stop loss insurance;

(2) Be a subsidiary of a health insurance issuer or issuer of stop loss insurance;

* * * * *

(4) Receive any consideration directly or indirectly from any health insurance issuer or issuer of stop loss insurance in connection with the enrollment of any individuals or employees in a QHP or a non-QHP.

* * * * *

■ 3. Section 155.215 is added to read as follows:

§ 155.215 Standards applicable to Navigators and non-Navigator Assistance Personnel carrying out consumer assistance functions under §§ 155.205(d) and (e) and 155.210 in a Federally-facilitated Exchange and to non-Navigator Assistance Personnel Funded Through an Exchange Establishment Grant.

(a) *Conflict-of-Interest Standards.* The following conflict-of-interest standards apply in an Exchange operated by HHS during the exercise of its authority under 45 CFR 155.105(f) and to non-Navigator assistance personnel funded through an Exchange Establishment Grant under section 1311(a) of the Affordable Care Act:

(1) *Conflict-of-Interest Standards for Navigators.*

(i) All Navigator entities, including Navigator grant applicants, must submit to the Exchange a written attestation that the Navigator, including the Navigator's staff:

(A) Is not a health insurance issuer or issuer of stop loss insurance;

(B) Is not a subsidiary of a health insurance issuer or issuer of stop loss insurance;

(C) Is not an association that includes members of, or lobbies on behalf of, the insurance industry; and

(D) Will not receive any consideration directly or indirectly from any health insurance issuer or issuer of stop loss insurance in connection with the enrollment of any individuals or employees in a QHP or non-QHP.

(ii) All Navigator entities must submit to the Exchange a written plan to remain free of conflicts of interest during the term as a Navigator.

(iii) All Navigator entities, including the Navigator's staff, must provide information to consumers about the full range of QHP options and insurance affordability programs for which they are eligible.

(iv) All Navigator entities, including the Navigator's staff, must disclose to the Exchange and to each consumer who receives application assistance from the Navigator:

(A) Any lines of insurance business, not covered by the restrictions on participation and prohibitions on conduct in § 155.210(d), which the Navigator intends to sell while carrying out the consumer assistance functions;

(B) Any existing employment relationships, or any former employment relationships within the last 5 years, with any health insurance issuers or issuers of stop loss insurance or subsidiaries of health insurance issuers or issuers of stop loss insurance, including any existing employment relationships between a spouse or domestic partner and any health insurance issuers or issuers of stop loss insurance, or subsidiaries of health insurance issuers or issuers of stop loss insurance; and

(C) Any existing or anticipated financial, business, or contractual relationships with one or more health insurance issuers or issuers of stop loss insurance, or subsidiaries of health insurance issuers or issuers of stop loss insurance.

(2) *Conflict-of-Interest Standards for Non-Navigator Assistance Personnel Carrying Out Consumer Assistance Functions Under § 155.205(d) and (e).* All Non-Navigator entities or individuals authorized to carry out consumer assistance functions under § 155.205(d) and (e) must—

(i) Comply with the prohibitions on Navigator conduct set forth at § 155.210(d).

(ii) Submit to the Exchange a written attestation that the entity or individual:

(A) Is not a health insurance issuer or issuer of stop loss insurance;

(B) Is not a subsidiary of a health insurance issuer or issuer of stop loss insurance;

(C) Is not an association that includes members of, or lobbies on behalf of, the insurance industry; and

(D) Will not receive any consideration directly or indirectly from any health insurance issuer or issuer of stop loss insurance in connection with the enrollment of any individuals or employees in a QHP or non-QHP.

(iii) Submit to the Exchange a written plan to remain free of conflicts of interest while carrying out consumer assistance functions under § 155.205(d) and (e).

(iv) Provide information to consumers about the full range of QHP options and insurance affordability programs for which they are eligible.

(v) Disclose to the Exchange and to each consumer who receives application assistance from the entity or individual:

(A) Any lines of insurance business, not covered by the restrictions on participation and prohibitions on conduct in § 155.210(d), which the entity or individual intends to sell while carrying out the consumer assistance functions;

(B) Any existing employment relationships, or any former employment relationships within the last five years, with any health insurance issuers or issuers of stop loss insurance, or subsidiaries of health insurance issuers or issuers of stop loss insurance, including any existing employment relationships between a spouse or domestic partner and any health insurance issuers or issuers of stop loss insurance, or subsidiaries of health insurance issuers or issuers of stop loss insurance; and

(C) Any existing or anticipated financial, business, or contractual relationships with one or more health insurance issuers or issuers of stop loss insurance, or subsidiaries of health insurance issuers or issuers of stop loss insurance.

(b) *Training standards for Navigators and Non-Navigator Assistance Personnel carrying out consumer assistance functions under §§ 155.205(d) and (e) and 155.210.* The following training standards apply in an Exchange operated by HHS during the exercise of its authority under § 155.105(f), and to non-Navigator assistance personnel funded through an Exchange Establishment Grant under section 1311(a) of the Affordable Care Act.

(1) *Certification and recertification standards.* All individuals or entities who carry out consumer assistance functions under §§ 155.205(d) and (e) and 155.210, including Navigators, must meet the following certification and recertification requirements.

(i) Obtain certification by the Exchange prior to carrying out any consumer assistance functions under §§ 155.205(d) and (e) or 155.210;

(ii) Register for and complete a HHS-approved training;

(iii) Following completion of the HHS-approved training described in paragraph (b)(1)(ii) of this section, complete and achieve a passing score on all approved certification examinations prior to carrying out any consumer assistance functions under §§ 155.205(d) and (e) or 155.210;

(iv) Obtain continuing education and be certified and/or recertified on at least an annual basis; and

(v) Be prepared to serve both the individual Exchange and SHOP.

(2) *Training module content standards.* All individuals who carry out the consumer assistance functions under §§ 155.205(d) and (e) and 155.210 must receive training in the following subjects:

(i) QHPs (including the metal levels described at § 156.140(b)), and how they operate, including benefits covered, payment processes, rights and processes for appeals and grievances, and contacting individual plans;

(ii) The range of insurance affordability programs, including Medicaid, the Children's Health Insurance Program (CHIP), and other public programs;

(iii) The tax implications of enrollment decisions;

(iv) Eligibility requirements for premium tax credits and cost-sharing reductions, and the impacts of premium tax credits on the cost of premiums;

(v) Contact information for appropriate federal, state, and local agencies for consumers seeking additional information about specific coverage options not offered through the Exchange;

(vi) Basic concepts about health insurance and the Exchange; the benefits of having health insurance and enrolling through an Exchange; and the individual responsibility to have health insurance;

(vii) Eligibility and enrollment rules and procedures, including how to appeal an eligibility determination;

(viii) Providing culturally and linguistically appropriate services;

(ix) Ensuring physical and other accessibility for people with a full range of disabilities;

(x) Understanding differences among health plans;

(xi) Privacy and security standards applicable under § 155.260 for handling and safeguarding consumers' personally identifiable information;

(xii) Working effectively with individuals with limited English proficiency, people with a full range of disabilities, and vulnerable, rural, and underserved populations;

(xiii) Customer service standards;

(xiv) Outreach and education methods and strategies; and

(xv) Applicable administrative rules, processes and systems related to Exchanges and QHPs.

(c) *Providing Culturally and Linguistically Appropriate Services (CLAS Standards).* The following standards will apply in an Exchange operated by HHS during the exercise of its authority under § 155.105(f) and to non-Navigator assistance personnel funded through an Exchange Establishment Grant under section 1311(a) of the Affordable Care Act. To ensure that information provided as part of any consumer assistance functions under §§ 155.205(d) and (e) or 155.210 is culturally and linguistically appropriate to the needs of the population being served, including individuals with limited English proficiency as required by §§ 155.205(c)(2) and 155.210(e)(5), any entity or individual carrying out these functions must:

(1) Develop and maintain general knowledge about the racial, ethnic, and cultural groups in their service area, including each group's diverse cultural health beliefs and practices, preferred languages, health literacy, and other needs;

(2) Collect and maintain updated information to help understand the composition of the communities in the service area, including the primary languages spoken;

(3) Provide consumers with information and assistance in the consumer's preferred language, at no cost to the consumer, including the provision of oral interpretation of non-English languages and the translation of written documents in non-English languages when necessary to ensure meaningful access. Use of a consumer's family or friends as oral interpreters can satisfy the requirement to provide linguistically appropriate services only when requested by the consumer as the preferred alternative to an offer of other interpretive services;

(4) Provide oral and written notice to consumers with limited English proficiency informing them of their right to receive language assistance services and how to obtain them;

(5) Receive ongoing education and training in culturally and linguistically appropriate service delivery; and

(6) Implement strategies to recruit, support, and promote a staff that is representative of the demographic characteristics, including primary languages spoken, of the communities in their service area.

(d) *Standards ensuring access by persons with disabilities.* The following standards related to ensuring access by people with disabilities will apply in an Exchange operated by HHS during the exercise of its authority under § 155.105(f), and to non-Navigator

assistance personnel funded through an Exchange Establishment Grant under section 1311(a) of the Affordable Care Act. Any entity or individual carrying out any consumer assistance functions under §§ 155.205(d) and (e) or 155.210, and in accordance with § 155.205(c), must:

(1) Ensure that any consumer education materials, Web sites, or other tools utilized for consumer assistance purposes, are accessible to people with disabilities, including those with sensory impairments, such as visual or hearing impairments, and those with mental illness, addiction, and physical, intellectual, and developmental disabilities;

(2) Provide auxiliary aids and services for individuals with disabilities, at no cost, where necessary for effective communication. Use of a consumer's family or friends as interpreters can satisfy the requirement to provide auxiliary aids and services only when requested by the consumer as the preferred alternative to an offer of other auxiliary aids and services;

(3) Provide assistance to consumers in a location and in a manner that is physically and otherwise accessible to individuals with disabilities;

(4) Ensure that legally authorized representatives are permitted to assist an individual with a disability to make informed decisions;

(5) Acquire sufficient knowledge to refer people with disabilities to local, state, and federal long-term services and supports programs when appropriate; and

(6) Be able to work with all individuals regardless of age, disability, or culture, and seek advice or experts when needed.

(e) *Monitoring.* Any Exchange operated by HHS during the exercise of its authority under § 155.105(f) will monitor compliance with the standards in this section and the requirements of §§ 155.205(d) and (e) and 155.210.

Dated: March 13, 2013.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: March 25, 2013.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2013–07951 Filed 4–3–13; 11:15 am]

BILLING CODE 4120–01–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 575

[Docket No. NHTSA–2012–0180]

New Car Assessment Program (NCAP)

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Request for comments.

SUMMARY: The U.S. New Car Assessment Program (NCAP) provides comparative information on the safety of new vehicles to assist consumers with vehicle purchasing decisions and encourage motor vehicle manufacturers to make safety improvements. To maintain the relevance and effectiveness of NCAP, NHTSA has periodically updated the program, most recently in model year 2011.

In response to the rapid development of vehicle safety technologies, especially in the area of crash avoidance, the agency is once again requesting public comments in order to help identify the potential areas for improvement to the program that have the greatest potential for producing safety benefits. This notice lists and describes potential areas of study for improving NCAP. The agency will use the comments it receives to aid it in developing a notice proposing near term upgrades to NCAP. The agency will also use the comments received in response to this notice to help it in developing a draft 5-year plan for the NCAP program outlining research that the agency plans to conduct as well as longer term upgrades it intends to pursue making to NCAP.

DATES: You should submit your comments early enough to ensure that Docket Management receives them no later than July 5, 2013.

ADDRESSES: Comments should refer to the docket number above and be submitted by one of the following methods:

- *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal Holidays.
- *Instructions:* For detailed instructions on submitting comments and additional information on the rulemaking process, see the Public Participation heading of the **SUPPLEMENTARY INFORMATION** section of this document. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.
- *Privacy Act:* Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78). For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* or the street address listed above. Follow the online instructions for accessing the dockets.

FOR FURTHER INFORMATION CONTACT: For crashworthiness issues, you may contact Ms. Jennifer N. Dang, Division Chief, New Car Assessment Program, Office of Crashworthiness Standards (Telephone: 202–493–0598). For crash avoidance and advanced technology issues, you may contact, Mr. Clarke Harper, Crash Avoidance NCAP Coordinator (Telephone: 202–366–1810). For legal issues, you may contact Mr. Steve Wood, Office of Chief Counsel (Telephone: 202–366–2992). You may send mail to any of these officials at the National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE., NVS–100, West Building, Washington, DC 20590–0001.

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I. Executive Summary

The NHTSA's New Car Assessment Program (NCAP) provides vehicle safety information that enables consumers to compare the safety performance and features of new vehicles. This helps consumers in making their new vehicle purchasing decisions and encourages manufacturers to improve the safety aspects of existing vehicle designs and include new or better safety technologies in future vehicle designs. As recently as the 2011 model year (MY), NHTSA upgraded NCAP to increase the stringency of the criteria that must be met to achieve high safety ratings and to provide consumers with more vehicle safety information. These program enhancements created additional market forces to improve vehicle safety. In recognition that technology and manufacturers will catch up with the safety performance criteria in even the enhanced version of NCAP, the agency seeks to take additional steps to encourage even more vehicle safety improvements.

This notice discusses the various subject areas on which NHTSA is seeking comments and information with respect to their future potential as an enhancement to NCAP. Some of the areas are supported by current research; others, if pursued, would require time and additional work by the agency. The agency seeks information and public comment about each area. Additionally, we seek suggestions regarding other program improvements not listed in this notice. We are seeking this information to help us plan future enhancements to the NCAP program that will create additional incentives for manufacturers to continually improve vehicle safety. We request information on such matters as safety benefits, field experience, test procedures, and progress in the development of crash avoidance technologies as well as crashworthiness activities. All of this information will be helpful in guiding us to develop future plans for NCAP improvements. At that time, we will again seek additional public comment.

The agency presents each area of interest in very brief and simple form (without going into details about benefits, tests, costs, or design concerns) in order to begin the process of identifying and prioritizing the potential areas for improving NCAP. The subjects discussed are also not listed in any particular priority order, nor should the list be construed as a final list of items for consideration. The agency welcomes comments on areas that are not listed in this notice, but are areas that commenters believe we should consider for future study and inclusion into NCAP.

This notice is the first step in a multi-step process of planning the next improvements to NCAP. After we receive comments, we will evaluate the status of all areas listed in this notice, plus any new areas that were provided by public comments. We will then use this information to develop a draft research plan and future proposals. Specifically, we plan to publish in the **Federal Register** a draft 5-year plan that may also include a draft proposal for near term upgrades to the NCAP program. This will be followed by a final 5-year plan and final decision notice on the near term upgrades, if appropriate.

II. Background

The NHTSA's NCAP provides comparative information on the safety performance and features of new vehicles to assist consumers with their vehicle purchasing decisions, to encourage manufacturers to improve the current safety performance and features of new vehicles, and to stimulate the addition of new safety features. NHTSA established NCAP in 1978 in response to Title II of the Motor Vehicle Information and Cost Savings Act of 1972. Beginning in MY 1979, NHTSA began rating passenger vehicles for frontal impact safety based on injury readings from dummies during crash tests. The agency added crash tests and ratings for side impact safety beginning in MY 1997. A rating system for rollover resistance was added in MY 2001 based on a vehicle's measured static properties as reflected in a calculation known as the Static Stability Factor (SSF). Beginning in MY 2004, rollover resistance ratings were amended to present the rating, based on not only the SSF but also the results of a dynamic vehicle test.

On January 25, 2007, NHTSA published a **Federal Register** notice announcing a public hearing and requesting comments on an agency report titled, ''The New Car Assessment Program (NCAP) Suggested Approaches for Future Enhancements.'' [1] Following the receipt of written comments and testimony at a March 7, 2007 public hearing, NHTSA published a notice on July 11, 2008, announcing specific changes to NCAP.[2] The agency made frontal and side crash ratings criteria more stringent by upgrading test dummies, establishing new injury criteria, adding a new side pole crash test, and creating a single overall vehicle score that reflects a vehicle's combined frontal crash, side crash, and rollover ratings.

In addition, the agency added information about the presence of advanced crash avoidance technologies in vehicles to NCAP. Technologies shown to have a safety benefit and that meet NHTSA's performance criteria are recommended to consumers on *www.safercar.gov* where all NCAP ratings are posted. The agency implemented these NCAP enhancements beginning with MY 2011.

At the time of these upgrades, various technologies began to develop in the field of automotive safety, some of which have become concurrent programs that may affect the same target crashes as advanced crash avoidance technologies. For example, researchers are making progress on two approaches to detecting and avoiding various potential crashes that may result in long-term crash and injury reductions: vehicle-to-vehicle communications (V2V) and advanced vehicle automation that may lead to various forms of self-driving vehicles. At this time, it is too soon to know how quickly these various advances in crash avoidance will develop and whether they will complement each other or progress independently. If either or both of these streams of innovation come to fruition, they could complement each other and increase the crash avoidance potential. NHTSA will decide in 2013 what its next steps will be with regard to light vehicle V2V technology. The agency is also monitoring closely developments that could lead to self-driving cars. So,

[1] 72 FR 3473 (January 25, 2007) (Docket No. NHTSA–2006–26555–0006).

[2] 73 FR 40016 (July 11, 2008) (Docket No. NHTSA–2006–26555–0114).

the agency has been carefully monitoring the progress of research programs that are on the horizon.

Motor vehicle manufacturers have made improvements to existing safety technologies since the notice upgrading the NCAP program was published in 2008. Since that time, new areas of innovation have emerged. Some of these technological innovations in vehicle safety have the potential to offer substantial safety benefits. The agency is issuing this notice to solicit comment on which emerging safety technologies offer the greatest promise in terms of agency research and inclusion in NCAP. We are also soliciting feedback on possible ways for NCAP to provide better consumer information. Our next steps are to use information gathered from the public in response to this notice and data from our research efforts to develop a draft 5-year plan and potentially propose near-term enhancements to the program.

III. Comments Requested

A brief summary of each of the safety and consumer information program areas under consideration is provided in the next section. We recognize that some of the following areas of study are better positioned to yield enhancements into NCAP sooner than others. Thus, depending on the amount of additional research that must be performed for some of the following areas of studies, we note that some areas could be considered for NCAP over the near term, and others would be need to be revisited as the research progresses. If there are areas that are not included in the list of areas from which enhancements to the NCAP could be possible, please identify those areas in your comments.

In general, there are four prerequisites for considering an area for adoption as a new NCAP enhancement. First, a safety need must be known or be capable of being estimated based on what is known. Next, vehicle and equipment designs must exist or at least be anticipated in prototype designs that are capable of mitigating the safety need. Third, a safety benefit must be estimated, based on the anticipated performance of the existing or prototype design. Finally, it must be feasible to develop a performance-based objective test procedure to measure the ability of the vehicle technology to mitigate the safety issue.[3]

Below is a list of general questions that the agency requests commenters to answer for each of the subject areas summarized in this notice. Commenters are encouraged to use these questions as the basis for shaping their comments on each of the areas. Information provided by commenters will assist the agency in deciding which areas should be included in the agency's draft 5-year plan or possibly proposed as one of a number of near term enhancements to NCAP. The agency has the following general questions for each area of study described in the next section:

- Is there a safety benefit that could be obtained and that can be demonstrated in the form of projected lives saved and/or injuries prevented and crashes reduced?
- Are there objective test procedures or industry standards that would measure performance differences?
- Are the relevant vehicle safety improvements or technologies that would be encouraged sufficiently mature for mass production (i.e., product repeatability and reliability)?
- Is there research to support incorporating the area into NCAP?
  - Can a test procedure be developed that would enable the agency to comparatively rate the improvements or technologies encouraged by a suggested improvement to NCAP?
  - Are there data to support a robust estimate of the potential safety benefits (in terms of crashes prevented and lives saved/injuries prevented)?
- Would the suggested areas of study be ones for which NCAP could create the market forces necessary to encourage the adoption of particular vehicle safety improvements or technology?
  - In what manner should the consumer information about the suggested areas of study be presented so as to create the market forces necessary to encourage the relevant safety improvements or technologies?
- Would the potential change or addition to NCAP result in consumers getting timely and meaningful information?

We note that there are three areas on which the agency has already separately sought public comment or is engaged in research: Crash Imminent Braking (CIB) and Dynamic Brake Support (DBS),[4] the Vehicle-Child Restraint System (CRS) Fit Program,[5] and the Monroney label consumer research. In the case of both CIB/DBS and the Vehicle-CRS Fit Program, the agency has already separately sought comment, and the deadline for the receipt of comments has passed. The agency is now reviewing the comments. The agency is currently conducting consumer research on the Monroney label. A **Federal Register** notice seeking public comment on possible future changes to the Monroney label will be published when that research is complete. Given these ongoing efforts, the agency is not seeking through this notice to obtain additional comments on these three areas. The agency urges commenters to address areas other than the three areas mentioned above.

The next two sections discuss potential areas of study for improving safety and providing better consumer information.

IV. Subject Areas Under Consideration for Possible Inclusion or Refinement

a. Crash Avoidance and Post-Crash Technology Areas Under Consideration

In this section, the agency has included the advanced crash avoidance or advanced driver assistance technologies that we believe are the most common crash avoidance approaches being discussed today by either the automotive industry or the agency. We have also included post-crash technology.

i. Warning Technologies

1. Blind Spot Detection

The agency has been studying blind spot detection (BSD) technology.[6] Blind spots are areas toward the rear and the side of the vehicle that are not visible to the driver in any mirror or that are not within the peripheral vision of the driver. BSD systems warn drivers of the presence of vehicles that are in adjacent lanes, but cannot be seen because those vehicles are in their vehicle's blind spots. The usual circumstance in which warnings are provided is when a driver is steering into an adjacent parallel lane and cannot see that there is a moving vehicle, such as another car or a motorcycle, in that lane moving at approximately the same speed and slightly behind the driver's vehicle.

Typically, radar sensors in a BSD system detect vehicles, including motorcycles, in adjacent lanes. When a driver starts to make an intentional or unintentional lane change, an alert is

[3] The agency's July 11, 2008 notice announcing enhancements to NCAP discussed how the agency applied these three factors to particular technologies when we decided to promote electronic stability control (ESC), lane departure warning (LDW), and forward collision warning (FCW) to consumers through NCAP. 73 FR 40016 (July 11, 2008).

[4] 77 FR 39561 (July 3, 2012) (Docket No. NHTSA–2012–0057–0002).

[5] 76 FR 10637 (February 25, 2011) (Docket No. NHTSA–2010–00062–0001) and 76 FR 16472 (March 23, 2011) (Docket No. NHTSA–2010–00062–0003) correcting comment period deadline.

[6] Swenson, et al., ''Safety Evaluation Of Lane Change Collision Avoidance Systems Using The National Advanced Driving Simulator,'' 19th International Technical Conference on the Enhanced Safety of Vehicles, 2005, Paper 05–0249.

activated to warn the driver of the presence of a vehicle or vehicles that are in adjacent lanes and in the vehicle's side blind spot. The driver is warned using audio, visual or haptic warnings. As currently designed, BSD systems only warn the driver; they do not initiate automatic evasive maneuvers.

Blind spot detection systems are already being installed in some vehicle models as optional equipment. These systems are not regulated, nor are the warning systems standardized. The degree of sensitivity as to when to warn the driver is at the discretion of each vehicle manufacturer. We are not aware of any performance tests that exist for this technology. If commenters suggest blind spot detection as an area for incorporation in NCAP, the agency would be particularly interested in comments regarding methods of comparatively evaluating BSD systems (e.g., the detection reliability, the driver interface, etc.) and estimation of safety benefits.

2. Advanced Lighting

The subject of adding advanced frontal lighting to NCAP has been discussed for almost a decade.[7] Advanced frontal lighting can provide enhanced nighttime visibility. For example, advanced headlights currently available in production vehicles can aid drivers who are turning their vehicles by swiveling and providing more light in the direction in which the vehicle is turning.

We note that some advanced lighting technologies in production in other parts of the world are not currently permitted in the U.S. It is not the intention of this notice to promote or solicit comments on lighting systems that do not meet the current applicable Federal motor vehicle safety standards (FMVSSs). However, comments are requested on potential advanced frontal lighting systems that would meet FMVSS No.108, ''Lamps, reflective devices, and associated equipment.'' What are the potential systems and are there data that quantify the potential safety benefits?

ii. Intervention Technologies

1. Lane Departure Prevention

Lane departure prevention, or automatic lane-keeping, builds upon (or expands the safety potential of) lane departure warning systems by providing steering and/or braking input to the vehicle to correct unintentional drifting across lane markers. If commenters suggest lane departure prevention as an area for incorporation in NCAP, the agency would be particularly interested in comments regarding methods of comparatively evaluating such systems. In addition, comments are requested on the comparative benefits of lane departure systems that automatically intervene versus systems that issue warnings only.

2. Crash Imminent Braking (CIB) and Dynamic Brake Support (DBS)

The agency has been studying forward collision advanced braking technologies that provide various types of automatic braking in response to an impending crash. Such technologies show promise for enhancing the safety of vehicles by helping drivers to avoid crashes or by reducing the effects of crashes. Forward collision advanced braking technologies, in particular Crash Imminent Braking (CIB) and Dynamic Brake Support (DBS), are designed to address the most prevalent type of two-vehicle collision: front-to-rear collisions.

In a July 3, 2012 request for comments notice,[8] NHTSA preliminarily estimated the annual number of lives saved for DBS alone would be 3 to 19 lives and CIB alone would be 38 to 63 lives, upon full market penetration of these technologies.[9] As indicated earlier, today's notice is not asking for a repeat of comments submitted in response to the July 3, 2012 notice.

3. Automatic Pedestrian Detection and Braking (Frontal and Rearward)

Pedestrian detection and automatic braking are systems that are aimed to avoid or minimize pedestrian impacts and injuries. Such systems can provide both frontal and rearward pedestrian detection and automatic braking. Systems are already in production for low speed front and rear pedestrian impact prevention in some vehicle models.

These technologies use sensing systems similar to that are used for vehicle and lane marker detection. Different technologies are currently being implemented and different test procedures are being developed worldwide, although some test procedure complexities still exist. One example of a test procedure complexity is the need for a crash avoidance test dummy that would provide a radar and/or camera recognition signature that approximates that of a human and is durable enough to withstand any testing impacts. Comments are requested on methods of addressing and resolving these complexities.

iii. Crash Notification Technologies

Automatic Collision Notification (ACN) is a vehicle system that detects severe crashes and their location and automatically notifies a public safety answering point (PSAP) or a 9–1–1 call center either directly or through a third party. Crashes are detected by various vehicle sensors, and an ACN system notification typically occurs in crashes severe enough to result in air bag or seat belt pretensioner deployment. The location of the crash is transmitted using a global positioning system (GPS) technology. The notification that ACN systems can provide allows for earlier arrival of emergency personnel.

Advanced Automatic Collision Notification (AACN) systems evolved from ACN systems. The additional data elements AACN systems can transmit include, but are not limited to, prediction of injury severity, crash delta-V (velocity change during the crash), direction of impact, safety belt status, air bag deployment status, number of impact events, and the occurrence of a rollover. The Centers for Disease Control (CDC) convened a series of meetings of the National Expert Panel on Field Triage to consider the potential contributions of AACN. The panel concluded that AACN shows promise in improving health outcomes for severely injured crash patients by: predicting the likelihood of serious injury in vehicle occupants; decreasing response times by emergency medical personnel; assisting with field triage destination and transportation decisions; and decreasing time to definitive trauma care.

However, the data elements and the algorithms for predicting injury are not currently standardized. NHTSA and the CDC are currently exploring a wide range of issues relating to AACN and evaluations of potential standards for data transmission and injury severity prediction and considerations for system specifications and evaluations. An agency decision regarding next steps for AACN is planned for 2013.[10]

b. Crashworthiness Areas Under Consideration

i. Rear Seat Occupants

In recent years, improvements that have been made to the front seat crash environment have significantly decreased the risk of injuries and

[7] ''Summary Report of NHTSA's Forward Lighting Research Program,'' DOT HS 811 007, July 2008.

[8] 77 FR 37951 (July 3, 2012) (Docket No. NHTSA–2012–0057–0002).

[9] ''Forward Looking Advanced Braking Technologies Research Report,'' (Docket No. NHTSA 2012–0057–0001).

[10] ''NHTSA Vehicle Safety and Fuel Economy Rulemaking and Research Priority Plan 2011–2013,'' 76 FR 17808 (March 31, 2011) (Docket No. NHTSA–2009–0108).

fatalities for front seat occupants involved in frontal crashes. While exposure and injury rates for rear seat occupants overall are still relatively low, there is an emerging need to further understand the rear seat environment in recent model year vehicles, particularly in consideration of lighter and more compact vehicle designs. Comments are requested on the availability of any data that illustrate whether safety benefits can be realized through encouraging additional safety improvements and/or technologies including rear seat belt reminders targeted at protecting the rear seat environment.

One possibility is to dynamically test rear seats and seat belts in our frontal crash tests to evaluate their safety performance. Initially, this could be pursued with the 5th percentile adult female Hybrid III dummy. The agency plans to begin exploring the feasibility of testing with a 5th percentile Hybrid III dummy in the rear seat of frontal NCAP tests and the feasibility of developing an associated rating system. Comments are requested as to other potential approaches.

ii. Silver Car Rating System for Older Occupants

As the U.S. population shifts in coming years, more vehicle drivers and passengers will be 65 and older. Typically, older vehicle occupants are less able than younger occupants to withstand crash forces when they are involved in a crash. Therefore, the agency is conducting workshops and developing comprehensive vehicle and behavioral strategies to improve older driver crash protection.

A ''silver car'' rating system in NCAP could be developed as a tool for providing crash safety information for older consumers. Such a rating system could be presented in addition to the primary five-star NCAP rating system. Ultimately, older consumers could use NCAP silver car rating information to help them select and purchase vehicles that would be potentially safer for them. For example, inflatable seat belts or technologies that help prevent low speed pedal misapplication may have potential benefits for older occupants. Comments are requested as to what types of modifications to the current test procedures or test thresholds would enable the program to specifically measure the crash forces that would be imparted to elderly vehicle occupants. Are there aspects of vehicle performance, currently not evaluated by NCAP that would particularly address the needs of older vehicle occupants?

iii. Pedestrian Protection

Pedestrian fatalities and injuries from motor vehicle crashes remain a relatively high number in the United States. In fact, pedestrian deaths (4,280) accounted for 13 percent of all traffic fatalities in motor vehicle traffic crashes in 2010.[11] This is a 4 percent increase from the number reported in 2009.[12] The agency is developing a rulemaking proposal based on Global Technical Regulation (GTR) No. 9, ''Pedestrian Safety.'' We are testing and evaluating the headform hood impact procedure. We are also evaluating the Flex-PLI legform in support of a decision on its incorporation into GTR No. 9. Comments are requested as to (1) whether the agency should consider incorporating future pedestrian crashworthiness requirements into NCAP, (2) what areas of light vehicles (e.g., bumpers, hoods, etc.) the agency should focus its efforts, and (3) how the agency should consider the crashworthiness requirements on vehicles with automatic pedestrian and braking systems. The agency is not requesting comments from this notice for the regulation process. As mentioned previously, the agency will use comments it receives from this notice to develop a notice proposing near term upgrades to NCAP and a draft 5-year plan for the NCAP program outlining research that the agency plans to conduct as well as longer term upgrades it intends to pursue making to NCAP.

iv. Improved Test Dummies and Injury Criteria

1. New Test Dummies: WorldSID, THOR, Hybrid III 95th Percentile Male

As part of its international harmonization efforts under the auspices of the United Nations Economic Commission for Europe World Forum for Harmonization of Vehicle Regulations (WP.29), the agency has been working with the Informal Working Group on Side Impact Dummies under Working Party on Passive Safety (GRSP) to develop a new family of side impact crash test dummies (known as the WorldSID dummies). These test devices are representative of the 50th percentile male and 5th percentile female. The goal in developing these dummies is to create worldwide harmonized test devices for side impact with enhanced injury assessment capabilities and improved durability, repeatability, and reproducibility.

Over the past several years, NHTSA has conducted an evaluation of the WorldSID 50th percentile male dummy. This evaluation has included, among other things, an assessment of the dummy's biofidelic response, its long-term durability, and the repeatability and reproducibility of test results. NHTSA is working with the international biomechanics community in a cooperative research effort to complete the development and evaluation of the WorldSID 5th percentile female dummy. Upon completion, responses from the WorldSID 50th male and 5th percentile female dummies under comparable conditions will be compared to those from the ES–2re and SID–IIs dummies, respectively, which are currently specified for use in FMVSS No. 214, ''Side impact protection,'' as well as in NCAP side impact tests.

In addition, the agency has been working on completing the development of the THOR 50th percentile male and 5th percentile female advanced frontal crash test dummies. Recent enhancements to the 50th percentile male dummy included modification to the head, neck, thorax, abdomen, pelvis, femur and knee. Injury risk curves and injury criteria for the dummy are under development. Work is planned to adapt updates made for the 50th percentile male dummy into the THOR 5th percentile female dummy. Agency decisions are planned in 2013 and 2014 for the THOR 50th percentile male and 5th percentile female dummies, respectively.

Finally, the agency is considering testing vehicles with a frontal test dummy that represents a large male as part of the NCAP effort to provide consumers with a broad spectrum of vehicle evaluation data. This dummy, referred to as the 95th percentile adult male Hybrid III dummy, represents a six foot two inch (6′2″) tall male weighing 223 pounds. Although this dummy is not currently specified in NHTSA's regulations, this dummy has been used for research studies and developmental testing for decades. Inclusion of the 95th percentile adult male dummy and its corresponding injury criteria in a consumer information program could provide larger consumers with information more applicable to their protection while riding in a vehicle. This would also encourage vehicle manufacturers to expand their crash protection envelopes to cover a broader range of occupant sizes.

Comments are requested on the suitability of incorporating the

[11] National Highway Traffic Safety Administration Traffic Safety Facts—2010 Data (DOT HS 811 625).

[12] National Highway Traffic Safety Administration Traffic Safety Facts—2009 Data (DOT HS 811 394).

aforementioned test dummies into NCAP. What effect would the incorporation of a particular test dummy have on the vehicle ratings? What other test dummy designs should the agency consider?

2. New injury criteria: BRIC, SID–IIs Thoracic and Abdomen, Lower Leg

The agency has been researching a new brain injury measure known as the Brain Injury Criteria (BRIC),[13] to protect vehicle occupants against brain injury with an emphasis on injuries that are rotationally-induced. BRIC utilizes instrumentation in the dummy headform to collect head rotational data that is ultimately used to predict injury risk. NHTSA is currently collecting headform rotational data in NCAP tests to gain an understanding of the new vehicle fleet performance. Predicted injury risk in the fleet testing will then be compared to real-world injury risk based on available field data. Such a criterion could be applied to the various NCAP crash testing programs (i.e., frontal, side pole, side moving deformable barrier).

The agency is also considering the merits of including thoracic and abdominal rib deflection injury criteria for the small female side impact dummy (i.e., the SID–IIs). Incorporating such criteria could encourage safety improvements that would mitigate injuries to body regions not currently regulated by safety standards or evaluated by the side NCAP rating scheme. The current SID–IIs crash test dummies are equipped for measuring these data and the agency collects and monitors them for all side NCAP crash tests. However, at the present time, NCAP simply adds footnotes to the vehicle safety rating information to inform consumers when excessive values are recorded.

The agency may also consider the merit of adding a lower leg injury criterion for the 50th percentile male Hybrid III dummy in the frontal NCAP rating scheme to drive vehicle countermeasures that would mitigate driver lower leg injuries and the associated societal cost. The THOR-Lx and THOR-FLx lower leg retrofit kits for use on the 50th percentile male and 5th percentile female adult Hybrid III dummies, respectively, are instrumentation tools under agency evaluation that would be used to measure the lower leg injury criterion.

Comments are requested as to whether there are other injury criteria that the agency should consider. Would the existing test dummies be sufficient for the suggested injury criteria? How should the agency incorporate ratings based on the new injury criteria in the manner that is useful to the consumer?

3. Refined Injury Criteria: Nij

Since the introduction of the frontal neck injury criterion, Nij, over a decade ago, the agency has been monitoring the correlation between Nij and real-world crash data. Specifically, we are looking at relevant neck injury field risk in frontal NCAP-type crashes using National Automotive Sampling System—Crashworthiness Data System (NASS-CDS) data. Furthermore, the agency has been analyzing existing biomechanical data and various neck injury risk curve alternatives. We are also assessing the role of these neck injury risk curves on recent NCAP test data (model years 2011–2012).[14]

v. New Test Protocols for Electric Vehicles

A growing number of electric vehicles that are or will be available in the market use lithium-ion (Li-ion) batteries for propulsion power. Because Li-ion battery technology is relatively new to the automotive industry, safety standards specific to the use of this technology in automotive applications are still under development. Although NHTSA is unaware of any real-world crashes involving Li-ion battery-powered vehicles that have resulted in a safety concern, the agency is focused on understanding the potential safety risks stemming from crashes involving these vehicles.

In the near term, the agency plans to research additional test protocols that will be run in addition to the existing FMVSS No. 305, ''Electric-powered vehicles: Electrolyte spillage and electrical shock protection,'' and NCAP test procedures of electric vehicles using Li-ion-battery propulsion systems.[15] The agency plans to examine the potential safety hazards associated with the health, stability, and functionality of the battery system after a vehicle is involved in a crash. Specifically, the protocol will examine the vehicle's ability to structurally protect the battery in a crash and the health of the battery and associated components. The information gathered from this evaluation will build on the agency's ongoing electric vehicle safety efforts and will help lay the groundwork for future research and/or regulation.

vi. Other Strategies

1. Comparative Barrier Testing for Frontal Rating

Star ratings for vehicles of widely differing masses and type cannot be directly compared using the full frontal rigid barrier crash test. The full frontal rigid barrier crash test represents a crash between two vehicles of similar weight and geometry. Thus, frontal crash test ratings of two vehicles cannot be compared unless those vehicles are in the same class and within 250 pounds of one another. Similarly, since the Overall Vehicle Score encompasses the frontal rating, the Overall Vehicle Scores of two vehicles cannot be compared unless the two vehicles have similar mass. Thus, there is a desire to provide consumers with a more useful tool for their vehicle purchasing decisions, (i.e., one that consumers can use to compare directly the safety of vehicles of widely varying weights and types). Potential changes may include changing the frontal barrier test configuration to provide a better safety comparison given the weight disparity among vehicles in the U.S. fleet.

2. Advanced Child Dummies, Family Star Rating

The agency is aware that consumers often wish to know which vehicles are the safest for their children. Thus, providing a crashworthiness rating for vehicles based on the protection they offer to both front seat adult occupants and rear seat child occupants would support consumer interests. Earlier this notice discussed adding a 5th percentile adult female Hybrid III dummy to the rear seat of frontal NCAP tests. An expansion of this concept would be to explore the potential for adding advanced child dummies to one or more of its crashworthiness test modes and explore the feasibility of providing consumers with a ''family star rating.'' NHTSA plans to use data obtained from the agency's biomechanics research to support the development and evaluation of an advanced 6-year-old child frontal impact dummy, followed by the 3- and 10-year-old child frontal impact dummies.[16]

[13] Takhounts et al., ''Kinematic Rotational Brain Injury Criterion (BRIC),'' 22nd International Technical Conference on the Enhanced Safety of Vehicles, 2011, Paper 11–0263.

[14] This activity is related to comments raised during the previous NCAP upgrade (i.e., regarding the non-zero offset in the Nij curve used to calculate injury risk for the purposes of computing star ratings).

[15] This effort is to improve our current post-crash laboratory test procedures for batteries to ensure that our test labs have the most current and complete safety protocols.

[16] NHTSA's Biomechanics Research Plan, 2011–2015 (DOT HS 811 474).

c. Potential Changes to the Rating System

i. Adjustment of Baseline Injury Risk

Safety ratings under the enhanced NCAP that went into effect for MY 2011 are based on how a vehicle's risk of injury reflected in NCAP tests compares to a baseline injury risk of approximately 15 percent for all crash types. The baseline injury risk was derived from agency crash data for MY 2007 and 2008 vehicles. In the July 11, 2008 **Federal Register** notice announcing the NCAP enhancements, the agency indicated that it would periodically review the crash performance of the vehicle fleet, as reflected by NCAP test data. Now is an appropriate time for such a review.

In the short time since the enhanced NCAP was implemented, the frontal and side crash test ratings of NCAP tested vehicles have improved. Crash data from newer model year vehicles could be used to reassess the baseline injury risk that is currently used to determine the respective crashworthiness safety ratings for the frontal and side crash test programs. Additionally, the rollover contribution to the baseline injury risk has changed due to the introduction of ESC in all new vehicles as of September 1, 2011. Rollover risk could be recalculated in the near future based on new data and a vehicle fleet equipped with ESC. (This is discussed further in the next section.)

ii. Update of the Rollover Risk Curve

The agency established a criterion in 2001 that reflected the risk of a rollover in a single-vehicle crash based primarily on two vehicle characteristics: The vehicle width at the tires and the height of the vehicle's center of gravity. The rollover risk derived from these measurements, known as a vehicle's Static Stability Factor (SSF), was based on 226,117 real-world crashes.[17] In 2003, the agency added a dynamic test to the rollover evaluation and updated the risk curve for the SSF model. This 2003 rollover risk was based on 293,000 single-vehicle crashes.[18] The SSF and the dynamic test created a slightly modified rollover risk rating for MY 2004 and newer vehicles. Subsequent to the creation of the SSF and dynamic test evaluations, manufacturers began a progressive conversion of the light vehicle fleet from a fleet with no anti-rollover technology to one equipped with ESC. Since September 1, 2011, all new light vehicles sold in the United States have been required to be equipped with ESC.[19]

In the 2008 NCAP upgrade notice, the agency stated that it would recalculate the risk of rollover and reformulate the rollover rating system to reflect the vehicle fleet change. However, since the accumulation of crash data for ESC-equipped vehicles has been progressing slowly, we have delayed the reformulation of the rollover rating system until a time when more crash data are available.

iii. Carry Back Ratings

Under the existing NCAP protocols, new model year vehicles that have no design changes from the previous model year can have their NCAP ratings carried over to the new model year. Every year, after reviewing annual submissions from the vehicle manufacturers, NHTSA determines which vehicle ratings should be carried over to the new model year without retesting. The issue of whether a particular rating should be carried over is considered independently for each aspect of performance tested under the NCAP program. For example, it is possible that, between model years, a model was changed in such a way as to make it appropriate for the model to have its frontal crash ratings carried over, but not its side crash ratings carried over. NHTSA uses carry over ratings to avoid the time and expense of unnecessary re-testing and to increase the percentage of new vehicles that have NCAP ratings each year. We are also considering a similar approach for advanced crash avoidance technologies. In other words, if the previous model year vehicle is equipped with an identical advanced technology system that received credit for meeting NHTSA's performance criteria, the current model year would also be given similar credit.

NHTSA is considering whether it would be appropriate to carry back ratings, i.e., apply the ratings of test vehicles produced in the new model year to similar vehicles produced in previous model year(s), but that were not rated. In other words, vehicle models that were tested in the new model year, but were not changed from and rated in the previous model year could have the new model year ratings applied to previous model year(s). Doing this would depend on whether the new model year design is identical[20] to the previous model year design. Similar to the carry over ratings policy, the carry back policy would provide increased consumer information.

V. Ideas Under Consideration for Providing Better Consumer Information

a. Focus Group Testing on Advanced Technologies

As part of the 2008 upgrade of NCAP, the agency performed focus group testing on the desire for advanced crash avoidance technology information. At that time, consumers indicated that they wanted to know if specific beneficial advanced technologies were provided on specific vehicle models. To that end, the agency identified three beneficial advanced technologies: Electronic stability control, lane departure warning, and forward collision warning and placed a description of and recommendation for each of them on the agency's Web site *www.safercar.gov*. For each of these technologies, the agency specified minimum performance criteria. If a vehicle model is equipped with one of the technologies and if the manufacturer self-certifies that the model meets the minimum performance criteria for that technology, the agency places a symbol illustrating that technology next to the entry for that model on *www.safercar.gov*.

Given the passage of time and rapid pace of electronic communications, the agency is planning to revisit how consumers would like advanced technology information presented to them. In 2013, we plan to conduct focus group testing to determine if consumers would like alternative methods of having advanced technology information communicated and if ratings of advanced technologies, rather than the current approach of recommending advanced technologies, are preferred.

b. Comprehensive Consumer Research on the Monroney Label

NHTSA plans to conduct comprehensive consumer research on the design and use of the NCAP safety ratings portion of the Monroney label.[21] Through this research, the agency will explore where consumers look for safety information and how consumers use the Monroney label when making their vehicle purchasing decisions. It will

[17] 68 FR 59290 (October 14, 2003) (Docket No. NHTSA–2001–9663; Notice 3).

[18] 68 FR 59258 (October 14, 2003) (Docket No. NHTSA–2001–9663; Notice 3).

[19] Multi-stage manufacturers and alterers were permitted to delay complying with the ESC requirement until September 1, 2012.

[20] Identical vehicle models are those that have not been redesigned with structural changes and are equipped with similar safety equipment (i.e., restraint systems, air bags, crash avoidance sensors, algorithms, etc.) from one model year to the next.

[21] Information Collection Request for the Consumer Research Program on the Monroney label (ICR Number 201112–2127–001), *www.reginfo.gov*.

also evaluate the Monroney label content comprehension and identify potential tradeoffs involved in alternative approaches. The results of this research will help guide effective changes to the safety ratings section of the Monroney label, and identify potential communication approaches to use in a consumer education program.

c. Vehicle-CRS Fit Program

As indicated in Section III of this notice, the agency has already separately sought public comment regarding the Vehicle-CRS Fit program in a **Federal Register** ''Request for comments'' notice published on February 25, 2011.[22] Thus, the agency is not seeking through this notice to obtain additional comments on this program. This proposed voluntary program is intended to have vehicle manufacturers evaluate CRSs for compatibility with a specific vehicle model based on a set of objective criteria. Vehicle manufacturers would provide NHTSA with a list of recommended CRSs that they have determined fit in their vehicles, and NHTSA would in turn publish that information. The agency plans to spot-check the CRS-vehicle combinations to ensure they actually comply with the requirements of the new voluntary Vehicle-CRS Fit program. A final decision notice for this program is currently being developed.

d. Child Seat Ease of Use Rating Program Upgrade

In response to Section 14(g) of the Transportation Recall Enhancement, Accountability and Documentation (TREAD) Act, NHTSA established a yearly Ease of Use assessment program for add-on child restraints. Since the program was established, the most notable improvements are ones that have been made to child restraint harness designs, labels and manuals. On February 1, 2008, the agency enhanced the program by including new rating features and criteria, adjusting the scoring systems, and using stars to display the Ease of Use ratings.

The agency is now considering additional improvements to the Ease of Use Program to address added CRS features that are not currently assessed, but may have an effect on usability. Additionally, it may be necessary to strengthen the current rating criteria since manufacturers continually make improvements to their products. Comments are requested on what additional CRS features should be addressed and what aspects of the current rating criteria should be strengthened.

[22] 76 FR 10637 (February 25, 2011) (Docket No. NHTSA–2010–00062–0001).

VI. Public Participation

How do I prepare and submit comments?

Your comments must be written and in English. To ensure that your comments are filed correctly in the docket, please include the docket number of this document in your comments.

Your comments must not be more than 15 pages long (49 CFR 553.21). NHTSA established this limit to encourage you to write your primary comments in a concise fashion. However, you may attach necessary additional documents to your comments. There is no limit on the length of the attachments.

Please submit one copy (two copies if submitting by mail or hand delivery) of your comments, including the attachments, to the docket following the instructions given above under **ADDRESSES**. Please note, if you are submitting comments electronically as a PDF (Adobe) file, we ask that the documents submitted be scanned using an Optical Character Recognition (OCR) process, thus allowing the agency to search and copy certain portions of your submissions.

How do I submit confidential business information?

If you wish to submit any information under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Office of the Chief Counsel, NHTSA, at the address given above under **FOR FURTHER INFORMATION CONTACT**. In addition, you may submit a copy (two copies if submitting by mail or hand delivery), from which you have deleted the claimed confidential business information, to the docket by one of the methods given above under **ADDRESSES**. When you send a comment containing information claimed to be confidential business information, you should include a cover letter setting forth the information specified in NHTSA's confidential business information regulation (49 CFR Part 512).

Will the agency consider late comments?

NHTSA will consider all comments received before the close of business on the comment closing date indicated above under **DATES**. To the extent possible, the agency will also consider comments received after that date.

You may read the comments received at the address given above under **ADDRESSES**. The hours of the docket are indicated above in the same location. You may also see the comments on the Internet, identified by the docket number at the heading of this notice, at *http://www.regulations.gov*.

Please note that, even after the comment closing date, NHTSA will continue to file relevant information in the docket as it becomes available. Further, some people may submit late comments. Accordingly, the agency recommends that you periodically check the docket for new material.

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

Issued on: March 28, 2013.

Christopher J. Bonanti,

Associate Administrator for Rulemaking.

[FR Doc. 2013–07766 Filed 4–4–13; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 216

[Docket No. 130221153–3153–01]

RIN 0648–BC78

Enhanced Document Requirements To Support Use of the Dolphin Safe Label on Tuna Products

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes to revise regulations under the Dolphin Protection Consumer Information Act (DPCIA) to enhance the requirements for documentation to support labels on tuna products that represent the product as dolphin-safe. This proposed rule would modify the requirements for the certifications that must accompany the Fisheries Certificate of Origin (FCO); change storage requirements related to dolphin-safe and non-dolphin-safe tuna

on board fishing vessels; create new requirements for processors, other than tuna canners, of tuna product labeled dolphin-safe; and modify the reporting requirements associated with tracking domestic tuna canning and processing operations. This proposed rule is intended to better ensure dolphin-safe labels comply with the requirements of the DPCIA and to ensure that the United States satisfies its obligations as a member of the World Trade Organization (WTO).

DATES: Comments must be submitted in writing by May 6, 2013.

ADDRESSES: You may submit comments, identified by NOAA–NMFS–2013–0016, by any of the following methods:

- *Electronic Submissions:* Submit all electronic public comments via the Federal eRulemaking Portal: *http://www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2013-0016,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit written comments to Rodney R. McInnis, Regional Administrator, NMFS Southwest Regional Office, 501 W. Ocean Blvd., Suite 4200, Long Beach, CA 90802.
- *Fax:* 562–980–4047, Attn: Rodney R. McInnis.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on www.regulations.gov without change. All personal identifying information (e.g., name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous). Attachments to electronic comments will be accepted in Microsoft Word, Excel, or Adobe PDF file formats only.

Written comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in this proposed rule may be submitted to the NMFS Southwest Region (SWR) and by email to *OIRA_Submission@omb.eop.gov,* or faxed to (202) 395–7285.

FOR FURTHER INFORMATION CONTACT: William Jacobson, NMFS SWR, 562–980–4035.

SUPPLEMENTARY INFORMATION:

Background

Enacted in 1990, the DPCIA (16 U.S.C. 1385) established a dolphin-safe labeling standard for tuna products. The law addressed a Congressional finding that ''consumers would like to know if the tuna they purchase is falsely labeled as to the effect of the harvesting of the tuna on dolphins.'' The DPCIA sets out minimum criteria for when tuna product producers, importers, exporters, distributors, or sellers may label their product dolphin-safe or with any other similar term or symbol suggesting that the tuna contained in the product were harvested using a method of fishing that is not harmful to dolphins. Specifically, the DPCIA prohibits producers, importers, exporters, distributers, or sellers from labeling as dolphin-safe any tuna product that was harvested: (i) ''on the high seas by a vessel engaged in driftnet fishing,'' (ii) in the eastern tropical Pacific Ocean (ETP) by purse seine vessels with a carrying capacity of 400 short tons or greater unless accompanied by a captain's statement and observer's statement that no dolphins were intentionally encircled during the trip and no dolphins were killed or seriously injured during the set, or (iii) outside the ETP by purse seine vessels unless the captain certifies that no dolphins were intentionally encircled during the trip (16 U.S.C. 1385(d)(1)). The ETP is defined as the waters of the Pacific Ocean bounded by 40E N. latitude, 40E S. latitude, 160E W. longitude and the coastlines of North, Central and South America (50 CFR 216.3).

In addition to the above, if the Secretary of Commerce identifies a purse seine fishery that has a regular and significant association between dolphins and tuna similar to the ETP, then tuna products containing tuna harvested in such a fishery may not be labeled dolphin-safe, unless a captain and observer certify that no dolphins were killed or seriously injured in the sets in which the tuna were harvested (16 U.S.C. 1385(d)(1)(B)(i)). Furthermore, if the Secretary of Commerce identifies any other fishery that has a regular and significant association between dolphins and tuna, then tuna products containing tuna harvested in such a fishery may not be labeled dolphin-safe, unless a captain and observer (if NOAA Fisheries determines that an observer statement would be ''necessary'') certify that no dolphins were killed or seriously injured in the sets or other gear deployments in which the tuna were harvested (16 U.S.C. 1385(d)(1)(D)).

The minimum standards described above apply to any tuna product labeled dolphin-safe. The DPCIA further directs the Secretary of Commerce to develop an ''official mark'' that may be used to label tuna products as dolphin safe under 16 U.S.C. 1385(d)(3)(A), and requires that tuna product labeled dolphin-safe using other than the official mark may be used only if the tuna were harvested during a set or other gear deployment in which no dolphin was killed or seriously injured, regardless of the area of harvest or the type of gear used (16 U.S.C. 1385(d)(3)(C)(i)). Finally, NOAA Fisheries has broad authority to issue regulations to implement the DPCIA, including specifically the authority to establish a domestic tracking and verification program that provides for the tracking of tuna labeled dolphin-safe (whether using the official mark or any other mark) and to adjust such regulations as appropriate to implement an international tracking and verification program (16 U.S.C. 1385(f)).

Under current regulations, an FCO is required to accompany each importation of tuna product and is required to be submitted to NOAA Fisheries. The dolphin-safe status of the importation is declared on the FCO by the exporter and is endorsed by the importer. For tuna caught by ETP large purse seine vessels, current regulations require, as a condition of labeling tuna dolphin-safe, that the importer attach a certification from the captain and an observer on board the vessel that no dolphins were killed or seriously injured in the sets in which the tuna were caught, and that no purse seine net was intentionally deployed on or used to encircle dolphins during the fishing trip in which the tuna were caught. For vessels using purse seine gear outside the ETP, current regulations require, as a condition of labeling tuna dolphin-safe, that the importer attach a certification from the captain that no purse seine net was intentionally deployed on or used to encircle dolphins during the fishing trip in which the tuna were caught. Also under current regulations, domestic tuna canners are required to submit to NOAA Fisheries monthly reports, which include the pertinent information found on an FCO, as well as additional vessel and transshipment information not found on an FCO, for all tuna received at the plant.

In 2008, Mexico initiated WTO dispute settlement proceedings challenging the U.S. dolphin-safe labeling scheme as a violation of provisions of the WTO's *General Agreement on Tariffs and Trade 1994* and *Agreement on Technical Barriers to*

Trade (TBT Agreement). Mexico challenged three U.S. measures: the DPCIA, Department of Commerce DPCIA regulations (50 CFR 216.91 through 216.92), and a federal court decision (*Earth Island Institute* v. *Hogarth,* 494 F.3d 757 (9th Cir. 2007)). The challenged measures establish conditions under which tuna products may voluntarily be labeled dolphin-safe. On June 13, 2012, the WTO Dispute Settlement Body (DSB) adopted the WTO panel and Appellate Body reports finding that the U.S. dolphin-safe labeling scheme (including the regulations that would be amended in this proposed rule) accords less favorable treatment to Mexican tuna products and therefore is inconsistent with Article 2.1 of the TBT Agreement. This conclusion was based on a finding that the U.S. measures did not set conditions for use of the label in a way that reflects the risks faced by dolphins in different oceans.

Proposed Action

This proposed rule would revise regulations at 50 CFR 216.91, to impose additional requirements regarding certifications to support the labeling of tuna products as dolphin-safe. This proposed rule would better ensure dolphin-safe labels comply with the requirements of the DPCIA, and would ensure conformity with U.S. WTO obligations by addressing the WTO Dispute Settlement Body's ruling. If adopted, this rule would require, as a condition of labeling tuna dolphin-safe, that the captain of the vessel and, where applicable, either a qualified and authorized observer or an authorized representative of a nation participating in the observer program on board the vessel, certify that no dolphins were killed or seriously injured in the sets or other gear deployments in which the tuna were caught. In addition, for vessels using purse seine gear outside the ETP, the rule would require, if applicable, the observer or an authorized representative of a nation participating in the observer program to certify that no purse seine net was intentionally deployed on or used to encircle dolphins during the fishing trip in which the tuna were caught as a condition of labeling the tuna dolphin-safe.

This proposed rule would also revise regulations at 50 CFR 216.93 to change storage requirements related to dolphin-safe and non-dolphin-safe tuna on board fishing vessels; to create requirements for processors, other than tuna canners, of tuna product labeled dolphin-safe; and to include modifications to a monthly receipts report that domestic tuna canners currently submit to NMFS.

Dolphin-safe Labeling Standards

Under current regulations at 50 CFR 216.91(a), statements and/or certifications must accompany any tuna product labeled dolphin-safe that includes tuna harvested: by a large purse seine vessel (greater than 400 short tons (362.8 metric tons (mt)) carrying capacity) in the ETP; by a purse seine vessel of any size outside of the ETP; or in any other fishery, identified by the Secretary of Commerce, where there is regular and significant mortality or serious injury of dolphins.

The Secretary of Commerce has not determined, to date, that any other fishery has a regular and significant association between dolphins and tunas similar to the association between dolphins and tuna in the ETP, or regular and significant mortality or serious injury of dolphins, and therefore NOAA Fisheries has not imposed the additional requirements for captain's and (where applicable) observer's statements described in paragraphs (d)(1)(B)(i) and (d)(1)(D) of the DPCIA. Furthermore, while paragraph (d)(3)(C)(i) of the DCPIA forbids the use of alternative dolphin-safe marks on any tuna product harvested during a gear deployment in which dolphins were killed or seriously injured, current regulations do not require a captain's or observer's statement to document that no such mortality or injury has occurred. The proposed changes are intended to better ensure consistency with the requirements of the DPCIA, and to ensure conformity with U.S. WTO obligations. This rule is issued under the Secretary's broad regulatory authority to implement the DPCIA and particularly to implement a domestic tuna tracking and verification program (see paragraph (f) of the DPCIA, 16 U.S.C. § 1385(f)) to ensure that tuna is not falsely labeled as to the effect of harvesting of the tuna on dolphins. It would expand the current requirement that captains, and in some cases observers, provide a statement that ''no dolphins were killed or seriously injured'' for all tuna product labeled dolphin-safe, not just tuna harvested by large purse seine in the ETP. NMFS proposes to revise 50 CFR 216.91(a) to require that for all tuna product labeled dolphin-safe (other than that harvested by large ETP purse seine vessels or vessels engaged in large-scale driftnet fishing, which would remain subject to current requirements): (1) The captain of the vessel harvesting tuna provide a statement that no dolphins were killed or seriously injured in the sets or other gear deployments in which the tuna were caught; (2) an authorized and qualified observer on board the vessel (if any) or an authorized representative of the nation participating in an authorized and qualified observer program (if any) provide a statement that no dolphins were killed or seriously injured in the sets or other gear deployments in which the tuna were caught and, if applicable, no purse seine net was intentionally deployed on or used to encircle dolphins during the fishing trip in which the tuna were caught; and (3) tuna caught in sets or other gear deployments designated as dolphin-safe be stored separately from tuna caught in non-dolphin-safe sets or other gear deployments from the time of capture through unloading.

NMFS will identify fisheries that are monitored by on-board observers participating in a national or international observer program that the Assistant Administrator, NOAA, has determined are qualified and authorized by the program authority to certify that no dolphins were killed or seriously injured in the sets or other gear deployments in which the tuna were caught. The Assistant Administrator's determination will be announced publicly through a notice published in the **Federal Register** and also on the NMFS Southwest Region Web site at *http://swr.nmfs.noaa.gov.* Only tuna harvested on fishing trips beginning after the effective date of the final rule will be subject to the new requirements for captain and, where applicable, observer statements. These new information collections (i.e., all the new statements and certifications), will become effective only after review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*

Any producer, importer, exporter, distributor, or seller of tuna product labeled under these proposed regulations would be subject to enforcement under section 5 of the Federal Trade Commission Act for including a dolphin-safe label on tuna product in the United States that fails to meet the standards for use of a dolphin-safe label as set forth in paragraph (d) of the DPCIA, 16 USC § 1385(d). Furthermore, the violations of the requirements under this proposed rule are enforceable under 18 U.S.C. 1001(a), which authorizes the imposition of penalties including fines or imprisonment for anyone who knowingly and willfully (1) falsifies, conceals, or covers up by any trick, scheme, or device a material fact; (2) makes any materially false, fictitious, or

fraudulent statement or representation; or (3) makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry.

Tracking and Verification Program

NMFS proposes to revise the regulations at 50 CFR 216.93 governing the tuna tracking and verification as it relates to U.S. citizens and U.S. vessels. First, this rule would remove the words ''purse seine'' from the introductory paragraph of 50 CFR 216.93, because all tuna included, or intended to be included, in tuna product labeled dolphin-safe are subject to the requirements, not only tuna harvested using the purse seine fishing method.

NMFS also proposes adding a paragraph heading to 50 CFR 216.93(c)(1) to clarify that proposed subparagraphs under 50 CFR 216.93(c)(1) pertain to ETP large purse seine vessels. NMFS proposes to redesignate 50 CFR 216.93(c)(1) as paragraph 216.93(c)(1)(i), and to revise the paragraph by removing the words ''ETP fishing trips'' and inserting instead the phrase ''fishing trips, any part of which included fishing in the ETP,'' to clarify the meaning of ''ETP fishing trip.'' This rule would require that tuna product labeled dolphin-safe in the United States that was harvested by purse seine gear anywhere (other than large purse seine vessels in the ETP, which would remain subject to the current regulations), be stored separately from tuna caught in non-dolphin-safe sets from the time of capture through unloading. Under this rule, tuna caught in sets where a dolphin died or was seriously injured must be stored in a well designated for that trip as non-dolphin-safe by the captain or, where applicable, by a qualified and authorized observer under § 216.91. Any tuna loaded into a well previously designated on the trip as non-dolphin-safe would be considered non-dolphin-safe tuna. The captain or a qualified and authorized observer under § 216.91 would change the designation of a dolphin-safe well to non-dolphin-safe if any tuna loaded into the well were captured in a set in which a dolphin died or was seriously injured. If a purse seine vessel has only one storage well, then the rule would require the use of netting or other material to keep dolphin-safe tuna and non-dolphin-safe tuna physically separate. NMFS is seeking comments from the industry on this concept of physically separating dolphin-safe tuna and non-dolphin-safe tuna through the use of netting or other material on purse seine vessels with only one storage well.

The proposed rule would require tuna offloaded to trucks, storage facilities, or carrier vessels to be loaded or stored in such a way as to maintain and safeguard the identification of the dolphin-safe or non-dolphin-safe designation of the tuna as it left the fishing vessel. NMFS does not expect a significant cost burden increase to operators of trucks, storage facilities, or carrier vessels in order to keep dolphin-safe tuna and non-dolphin-safe tuna separate, as the industry already uses methods (e.g., the use of netting, tarps, or separate totes or storage containers) to keep offloaded tuna sourced from different suppliers separate. Revisions to 50 CFR 216.93(c) are intended to better ensure that dolphin-safe related requirements are met.

NMFS proposes to revise the regulations that pertain to tuna harvested by vessels other than purse seine vessels, at 50 CFR 216.93(c)(3). This rule would require that tuna caught in sets or other gear deployments designated as dolphin-safe to be stored separately from tuna caught in non-dolphin-safe sets or other gear deployments from the time of capture through unloading. Tuna caught in sets or other gear deployments where a dolphin died or was seriously injured would be considered non-dolphin-safe tuna, and would be required to be kept physically separate from the dolphin-safe tuna by using netting, other material, or separate storage areas. The rule would require tuna offloaded to trucks, storage facilities, or carrier vessels to be loaded or stored in such a way as to maintain and safeguard the identification of the dolphin-safe or non-dolphin-safe designation of the tuna as it left the fishing vessel. The new requirements in 50 CFR 216.93(c)(3) are intended to better ensure that dolphin-safe related requirements are met.

NMFS proposes to remove the words ''ETP caught'' from 50 CFR 216.93(d)(1), so as not to limit tracking of domestic cannery operations to only ETP harvested tuna and tuna products.

Other proposed revisions include modifications to the monthly receipts report domestic canners submit under 50 CFR 216.93(d)(2)(i). This proposed rule would require the report to: (1) declare whether the tuna is eligible to be labeled dolphin-safe; (2) include the gear type of the harvesting method; and (3) enclose certifications required by 50 CFR 216.91 when the processor indicates the tuna is eligible to be labeled dolphin-safe under 50 CFR 216.91. These revisions are subject to review and approval by OMB under the PRA, 44 U.S.C. 3501 *et seq.*

NMFS also proposes to add requirements at 50 CFR 216.93(e) for tuna processors, other than tuna canners, to submit to NOAA monthly receipt reports: (1) Declaring whether the tuna is eligible to be labeled dolphin-safe; (2) identifying the gear type of the harvesting method; and (3) enclosing certifications required by 50 CFR 216.91 when the processor indicates the tuna is eligible to be labeled dolphin-safe under 50 CFR 216.91. These provisions would impose similar requirements on both tuna canners and other tuna processors. As with the new reporting requirements for tuna canners, these revisions are subject to review and approval by OMB under the PRA, 44 U.S.C. 3501 *et seq.* As a result of the insertion of this new paragraph, existing paragraphs at 50 CFR 216.93(e), (f), and (g) are proposed to be redesignated to paragraphs 50 CFR 216.93(f), (g), and (h).

Fisheries Certificates of Origin and Associated Certifications

To import tuna, tuna products, and certain other fish products into the United States, current regulations at 50 CFR 216.24(f)(3)(i) and (ii) require FCOs and associated certifications to be submitted to both U.S. Customs and Border Protection (CBP; Department of Homeland Security) and NMFS Southwest Region. The proposed changes in the dolphin-safe documentation requirements described above would also require NOAA to revise the FCOs. Specifically, the FCOs would direct importers to attach a captain's statement and, where applicable, a statement either by the observer or an authorized representative of a nation participating in the observer program, using information from the observer, certifying that no dolphins were killed or seriously injured in the sets or other gear deployments in which the tuna were caught, for: (1) Tuna not harvested with a purse seine net; (2) tuna harvested with a purse seine net outside the ETP; and (3) tuna harvested in the ETP by a purse seine vessel having a carrying capacity of 400 short tons (362.8 mt) or less. The revisions to the FCOs are subject to review and approval by OMB under the PRA, 44 U.S.C. 3501 *et seq.*

Classification

The NMFS Assistant Administrator has determined that this proposed rule is consistent with the DPCIA and other applicable laws, subject to further consideration after public comment.

This rule has been determined to be not significant for the purposes of E.O.

12866 by the OMB Office of Information and Regulatory Affairs.

Pursuant to 5 U.S.C. 605, part of the Regulatory Flexibility Act (RFA; 5 U.S.C. chapter 5), the Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration (SBA) that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. The basis for this certification is presented in the following paragraphs.

Description of Affected Entities and Small Entities

For purposes of the RFA, we assess the effects of the proposed regulations to three classes of entities: (1) Owners of U.S. tuna fishing vessels where the harvested tuna is labeled dolphin-safe and is sold in the United States; (2) U.S. tuna processors; and (3) importers of tuna and tuna products labeled dolphin-safe. We used the SBA's size standards established at 13 CFR part 121 to define the affected small entities: fishing vessels, tuna processors, and tuna importers. Using those standards, fishing vessels with less than $4 million in average annual receipts, tuna processors with fewer than 500 employees, and importers with fewer than 100 employees are considered small entities.

U.S. purse seine vessels that fish for tuna destined to become tuna product are divided into two size groups: (1) Vessels greater than 400 st (362.8 mt) carrying capacity (''large'' vessels); and (2) vessels of 400 st (362.8 mt) carrying capacity or less (''small'' vessels). Large vessels typically exceed $4 million in annual receipts, whereas small vessels have less than $4 million in annual receipts and would be considered small entities. From 2011—2012, the U.S. purse seine fleet, all of which fished in the Pacific Ocean, averaged 39 large vessels and 7 small vessels. About 1,930 U.S. non-purse seine commercial fishing vessels are authorized to fish for tuna in the Pacific Ocean per year, including: (1) vessels under Pacific Highly Migratory Species vessel permits (about 1,766 vessels); and (2) vessels based in Hawaii and the U.S. Pacific Islands, under High Seas Fishing Compliance Act permits (about 175 vessels). All of these are considered small entities in this analysis, and have less than $4 million in annual receipts.

There are 19 tuna canning manufacturers in the United States. Of these, 16 are considered small businesses, because they have fewer than 500 employees.

NMFS is unaware of any domestic tuna processor, other than canning operations, that labels tuna product as dolphin-safe.

There are an estimated 430 U.S. importers of tuna and tuna products per year. Of these, about 380 importers are considered small businesses, because they have fewer than 100 employees.

Impacts on Affected Entities

The proposed rule, if implemented, would apply additional documentation requirements to all three classes of affected entities; none of these reporting requirements would result in a significant economic effect. The time needed to gather and submit a written statement by the captain of the harvesting vessel and by the observer on board the vessel or by an authorized representative, if applicable, would be minimal (about 5 minutes each). An additional cost to provide the written statements would be about $0.10 for each one page written statement. Moreover, any additional costs to any entity resulting from this rule will be small (e.g. the cost associated with two pieces of netting or tarps, etc. for use in storage separation). Accordingly, as it pertains to the RFA, this rule will not have a significant economic impact on a substantial number of small entities. As a result, an initial regulatory flexibility analysis is not required and none has been prepared.

This proposed rule contains two collection-of-information requirements subject to review and approval by OMB under the PRA under control numbers 0648–0335 and 0648–0387. Revision of OMB control number 0648–0335, titled ''Fisheries Certificate of Origin,'' if approved, modifies the dolphin-safe status section of the FCO. The labor and cost burden due to this proposed rule on control number 0648–0335 is estimated to affect approximately 13,000 responses annually from 430 respondents. The cost and labor burdens are estimated to increase by $0.30 and 5 minutes respectively, per response. Revision of OMB control number 0648–0387, titled ''International Dolphin Conservation Program,'' if approved, requires information from tuna canners and tuna processors, other than canners, about the eligibility of tuna to be labeled dolphin-safe; the gear type used to harvest the tuna; and will contain certifications required by 50 CFR 216.91. The labor and cost burden due to this proposed rule on control number 0648–0387 is estimated to affect approximately 72 responses annually from 19 respondents. The cost and labor burdens are estimated to increase by $0.50 and 5 minutes respectively, per response. These collections have been submitted to OMB for approval. Public reporting burden estimates include the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection information.

Public comment is sought regarding: whether this proposed collection-of-information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the burden estimate; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collection-of-information, including through the use of automated collection techniques or other forms of information technology. Send comments on these or any other aspects of the collection-of-information to NMFS Southwest Region at the **ADDRESSES** above, and by email to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–7285.

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with a collection-of-information subject to the requirements of the PRA, unless that collection-of-information displays a currently valid OMB Control Number.

List of Subjects in 50 CFR Part 216

Commercial fisheries, Food labeling, Imports, Marine mammals, Reporting and recordkeeping requirements, Seafood.

Dated: April 2, 2013.

Alan D. Risenhoover,

Director, Office of Sustainable Fisheries, performing the functions and duties of the Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 216, subpart H is proposed to be amended as follows:

PART 216—REGULATIONS GOVERNING THE TAKING AND IMPORTING OF MARINE MAMMALS

■ 1. The authority citation for 50 CFR part 216, subpart H, continues to read as follows:

Authority: 16 U.S.C. 1385

■ 2. In § 216.91, revise paragraphs (a)(2)(ii) and (a)(4), and add a new paragraph (a)(5) to read as follows:

§ 216.91 Dolphin-safe labeling standards.

(a) * * *

(2) * * *

(ii) In any other fishery unless the products are accompanied as described in § 216.93(d), (e), or (f), as appropriate, by:

(A) A written statement executed by the Captain of the vessel certifying that no purse seine net was intentionally deployed on or used to encircle dolphins during the fishing trip in which the tuna were caught, and that no dolphins were killed or seriously injured in the sets in which the tuna were caught; and

(B) Where the Assistant Administrator has determined that observers participating in a national or international observer program are qualified and authorized to certify that no purse seine net was intentionally deployed on or used to encircle dolphins during the fishing trip in which the tuna were caught, and that no dolphins were killed or seriously injured in the sets in which the tuna were caught, and where such an observer is on board the vessel, a written statement executed by the observer, or by an authorized representative of a nation participating in the observer program based on information from the observer, certifying that no purse seine net was intentionally deployed on or used to encircle dolphins during the fishing trip in which the tuna were caught and that no dolphins were killed or seriously injured in the sets in which the tuna were caught. Any determination by the Assistant Administrator shall be announced in a notice published in the **Federal Register.** Determinations under this paragraph (a)(2)(ii)(B) will also be publicized on the Web site of the NMFS Southwest Region (*http://swr.nmfs.noaa.gov/*).

* * * * *

(4) *Other fisheries.* By a vessel in a fishery other than one described in paragraphs (a)(1) through (a)(3) of this section unless such product is accompanied as described in § 216.93(d), (e), or (f), as appropriate, by:

(i) A written statement executed by the Captain of the vessel certifying that no dolphins were killed or seriously injured in the sets or other gear deployments in which the tuna were caught;

(ii) Where the Assistant Administrator has determined that observers participating in a national or international observer program are qualified and authorized to certify that no dolphins were killed or seriously injured in the sets or other gear deployments in which the tuna were caught, and where such an observer is on board the vessel, a written statement executed by the observer, or by an authorized representative of a nation participating in the observer program based on information from the observer, certifying that no dolphins were killed or seriously injured in the sets or other gear deployments in which the tuna were caught. Any determination by the Assistant Administrator shall be announced in a notice published in the **Federal Register.** Determinations under this subparagraph will also be publicized on the Web site of the NMFS Southwest Region (*http://swr.nmfs.noaa.gov/*); and

(iii) In addition to the requirements of paragraphs (a)(4)(i) and (ii) of this section, in any other fishery that is identified by the Assistant Administrator as having a regular and significant mortality or serious injury of dolphins, a written statement executed by an observer participating in a national or international program acceptable to the Assistant Administrator, that no dolphins were killed or seriously injured in the sets or other gear deployments in which the tuna were caught, provided that the Assistant Administrator determines that such an observer statement is necessary.

(5) *All fisheries.* On a fishing trip during which any dolphin was killed or seriously injured, unless the tuna labeled dolphin-safe was caught in a set or other gear deployment was stored separately from tuna caught in non-dolphin-safe sets or other gear deployments by the use of netting, other material, or separate storage areas from the time of capture through unloading. If a purse seine vessel has more than one well used to store tuna, all tuna inside a well shall be considered non-dolphin-safe, if at any time non-dolphin-safe tuna is loaded into the well, regardless of the use of netting or other material inside the well.

* * * * *

■ 3. Section 216.93 is revised to read as follows:

§ 216.93 Tracking and verification program.

The Administrator, Southwest Region, has established a national tracking and verification program to accurately document the dolphin-safe condition of tuna, under the standards set forth in §§ 216.91 and 216.92. The tracking program includes procedures and reports for use when importing tuna into the United States and during U.S. fishing, processing, and marketing in the United States and abroad. Verification of tracking system operations is attained through the establishment of audit and document review requirements. The tracking program is consistent with the international tuna tracking and verification program adopted by the Parties to the Agreement on the IDCP.

(a) *Tuna tracking forms.* Whenever a U.S. flag tuna purse seine vessel of greater than 400 st (362.8 mt) carrying capacity fishes in the ETP, IDCP approved Tuna Tracking Forms (TTFs), bearing a unique number assigned to that trip, are used by the observer to record every set made during that trip. One TTF is used to record dolphin-safe sets and a second TTF is used to record non-dolphin-safe sets. The information entered on the TTFs following each set includes the date, well number, weights by species composition, estimated tons loaded, and additional notes, if any. The observer and the vessel engineer initial the entry as soon as possible following each set, and the vessel captain and observer review and sign both TTFs at the end of the fishing trip certifying that the information on the forms is accurate. TTFs are confidential official documents of the IDCP, consistent with Article XVIII of the Agreement on the IDCP, and the Agreement on the IDCP Rules of Confidentiality.

(b) *Dolphin-safe certification.* Upon request, the Office of the Administrator, Southwest Region, will provide written certification that tuna harvested by U.S. purse seine vessels greater than 400 st (362.8 mt) carrying capacity is dolphin-safe, but only if NMFS' review of the TTFs for the subject trip shows that the tuna for which the certification is requested is dolphin-safe under the requirements of the Agreement on the IDCP and U.S. law.

(c) *Tracking fishing operations.* (1) *ETP large purse seine vessel.* In the ETP by a purse seine vessel of greater than 400 st (362.8 mt) carrying capacity:

(i) During fishing trips, any part of which included fishing in the ETP, by purse seine vessels greater than 400 st (362.8 mt) carrying capacity, tuna caught in sets designated as dolphin-safe by the vessel observer must be stored separately from tuna caught in non-dolphin-safe sets from the time of capture through unloading. Vessel personnel will decide into which wells tuna will be loaded. The observer will initially designate whether each set is dolphin-safe or not, based on his/her observation of the set. The observer will initially identify a vessel fish well as dolphin-safe if the first tuna loaded into the well during a trip was captured in a set in which no dolphin died or was seriously injured. The observer will initially identify a vessel fish well as non-dolphin-safe if the first tuna loaded into the well during a trip was captured in a set in which a dolphin died or was

seriously injured. Any tuna loaded into a well previously designated non-dolphin-safe is considered non-dolphin-safe tuna. The observer will change the designation of a dolphin-safe well to non-dolphin-safe if any tuna are loaded into the well that were captured in a set in which a dolphin died or was seriously injured.

(ii) The captain, managing owner, or vessel agent of a U.S. purse seine vessel greater than 400 st (362.8 mt) returning to port from a trip, any part of which included fishing in the ETP, must provide at least 48 hours' notice of the vessel's intended place of landing, arrival time, and schedule of unloading to the Administrator, Southwest Region.

(iii) If the trip terminates when the vessel enters port to unload part or all of its catch, new TTFs will be assigned to the new trip, and any information concerning tuna retained on the vessel will be recorded as the first entry on the TTFs for the new trip. If the trip is not terminated following a partial unloading, the vessel will retain the original TTFs and submit a copy of those TTFs to the Administrator, Southwest Region, within 5 working days. In either case, the species and amount unloaded will be noted on the respective originals.

(iv) Tuna offloaded to trucks, storage facilities, or carrier vessels must be loaded or stored in such a way as to maintain and safeguard the identification of the dolphin-safe or non-dolphin-safe designation of the tuna as it left the fishing vessel.

(v) The handling of TTFs and the tracking and verification of tuna caught in the Convention Area by a U.S. purse seine vessel greater than 400 st (362.8 mt) carrying capacity shall be conducted consistent with the international tuna tracking and verification program adopted by the Parties to the Agreement on the IDCP.

(2) *Purse seine vessel other than ETP large purse seine vessel.* This paragraph (c)(2) applies to tuna product labeled dolphin-safe that includes tuna harvested in the ETP by a purse seine vessel of 400 st (362.8 mt) or less carrying capacity or by a purse seine vessel outside the ETP of any carrying capacity.

(i) Tuna caught in sets designated as dolphin-safe must be stored separately from tuna caught in non-dolphin-safe sets from the time of capture through unloading. Tuna caught in sets where a dolphin died or was seriously injured must be stored in a well designated as non-dolphin-safe by the captain or, where applicable, by a qualified and authorized observer under § 216.91. Any tuna loaded into a well previously designated non-dolphin-safe is considered non-dolphin-safe tuna. The captain or, where applicable, a qualified and authorized observer under § 216.91, will change the designation of a dolphin-safe well to non-dolphin-safe if any tuna are loaded into the well that were captured in a set in which a dolphin died or was seriously injured. If a purse seine vessel has only one well used to store tuna, dolphin-safe tuna must be kept physically separate from non-dolphin-safe tuna by using netting or other material. If a purse seine vessel has more than one well used to store tuna, all tuna inside a well shall be considered non-dolphin-safe, if at any time non-dolphin-safe tuna is loaded into the well, regardless of the use of netting or other material inside the well.

(ii) Tuna offloaded to trucks, storage facilities, or carrier vessels must be loaded or stored in such a way as to maintain and safeguard the identification of the dolphin-safe or non-dolphin-safe designation of the tuna as it left the fishing vessel.

(3) *Other vessels.* This paragraph (c)(3) applies to tuna product labeled dolphin-safe that includes tuna harvested by a vessel other than ones described in paragraphs (c)(1) or (c)(2) of this section:

(i) Tuna caught in sets or other gear deployments designated as dolphin-safe must be stored separately from tuna caught in non-dolphin-safe sets or other gear deployments from the time of capture through unloading. Dolphin-safe tuna must be kept physically separate from non-dolphin-safe tuna by using netting, other material, or separate storage areas. The captain or, where applicable, a qualified and authorized observer under § 216.91, must designate the storage areas for dolphin-safe and non-dolphin-safe tuna.

(ii) Tuna offloaded to trucks, storage facilities, or carrier vessels must be loaded or stored in such a way as to maintain and safeguard the identification of the dolphin-safe or non-dolphin-safe designation of the tuna as it left the fishing vessel.

(d) *Tracking cannery operations.* (1) Whenever a U.S. tuna canning company in the 50 states, Puerto Rico, or American Samoa receives a domestic or imported shipment of tuna for processing, a NMFS representative may be present to monitor delivery and verify that dolphin-safe and non-dolphin-safe tuna are clearly identified and remain segregated. Such inspections may be scheduled or unscheduled, and canners must allow the NMFS representative access to all areas and records.

(2) Tuna processors must submit a report to the Administrator, Southwest Region, of all tuna received at their processing facilities in each calendar month whether or not the tuna is actually canned or stored during that month. Monthly cannery receipt reports must be submitted electronically or by mail before the last day of the month following the month being reported. Monthly reports must contain the following information:

(i) *Domestic receipts:* whether the tuna is eligible to be labeled dolphin-safe under § 216.91, species, condition (round, loin, dressed, gilled and gutted, other), weight in short tons to the fourth decimal, ocean area of capture (ETP, western Pacific, Indian, eastern and western Atlantic, other), catcher vessel, gear type, trip dates, carrier name, unloading dates, and location of unloading. Where the processor indicates the tuna is eligible to be labeled dolphin-safe under § 216.91, it must enclose the certifications required by that section.

(ii) *Import receipts:* In addition to the information required in paragraph (d)(2)(i) of this section, a copy of the FCO for each imported receipt must be provided.

(3) Tuna processors must report on a monthly basis the amounts of ETP-caught tuna that were immediately utilized upon receipt or removed from cold storage. This report may be submitted in conjunction with the monthly report required in paragraph (d)(2) of this section. This report must contain:

(i) The date of removal from cold storage or disposition;

(ii) Storage container or lot identifier number(s) and dolphin-safe or non-dolphin-safe designation of each container or lot; and

(iii) Details of the disposition of fish (for example, canning, sale, rejection, etc.).

(4) During canning activities, non-dolphin-safe tuna may not be mixed in any manner or at any time during processing with any dolphin-safe tuna or tuna products and may not share the same storage containers, cookers, conveyers, tables, or other canning and labeling machinery.

(e) *Tracking processor operations other than cannery operations.* U.S. tuna processors other than cannery operations engaged in processing tuna products, including frozen, dried, or smoked tuna products, must submit a report to the Administrator, Southwest Region that includes the information set out in paragraphs (d)(2) and (d)(3) of this section on a monthly basis for all tuna received at their processing

facilities that will be included in any tuna product labeled dolphin-safe.

(f) *Tracking imports.* All tuna products, except fresh tuna, that are imported into the United States must be accompanied as described in § 216.24(f)(3) by a properly certified FCO as required by § 216.24(f)(2). For tuna tracking purposes, copies of FCOs and associated certifications must be submitted by the importer of record to the Administrator, Southwest Region, within 10 calendar days of the shipment's entry into the commerce of the United States as required by § 216.24(f)(3)(ii).

(g) *Verification requirements.* (1) *Record maintenance.* Any exporter, transshipper, importer, processor, or wholesaler/distributor of any tuna or tuna products must maintain records related to that tuna for at least 2 years. These records include, but are not limited to: FCOs and required certifications, any reports required in paragraphs (a), (b), (d) and (e) of this section, invoices, other import documents, and trip reports.

(2) *Record submission.* Within 10 calendar days of receiving a shipment of tuna or tuna products, any exporter, transshipper, importer, processor, or wholesaler/distributor of tuna or tuna products must submit to the Administrator, Southwest Region, all corresponding FCOs and required certifications for those tuna or tuna products.

(3) *Audits and spot checks.* Upon request of the Administrator, Southwest Region, any exporter, transshipper, importer, processor, or wholesaler/distributor of tuna or tuna products must provide the Administrator, Southwest Region, timely access to all pertinent records and facilities to allow for audits and spot-checks on caught, landed, stored, and processed tuna.

(h) *Confidentiality of proprietary information.* Information submitted to the Assistant Administrator under this section will be treated as confidential in accordance with NOAA Administrative Order 216–100 ''Protection of Confidential Fisheries Statistics.''

[FR Doc. 2013–07990 Filed 4–4–13; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 78, No. 66
Friday, April 5, 2013

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

Food and Nutrition Service

Agency Information Collection Activities: Proposed Collection; Comment Request—Food Programs Reporting System

AGENCY: Food and Nutrition Service (FNS), USDA.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on this proposed information collection. This is a new collection for the electronic submission of programmatic and financial data through the Food Programs Reporting System (FPRS). The data is currently collected on approved Office of Management and Budget (OMB) forms.

DATES: Written comments must be received on or before June 4, 2013.

ADDRESSES: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions that were 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 the use of appropriate automated, electronic, mechanical or other technological collection techniques or other forms of information technology. Comments may be sent to: Maeve Myers, Food and Nutrition Service, U.S. Department of Agriculture, 3101 Park Center Drive, Room 706, Alexandria, VA 22302. Comments will also be accepted through the Federal eRulemaking Portal. Go to *http://www.regulations.gov,* and follow the online instructions for submitting comments electronically.

All responses to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will be a matter of public record.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this information collection should be directed to Maeve Myers at 703–305–2158.

SUPPLEMENTARY INFORMATION:

Title: Food Programs Reporting System (FPRS).

OMB Number: 0584–NEW.

Expiration Date: Not Yet Determined.

Type of Request: New collection.

Abstract: The Food and Nutrition Service (FNS) is the Federal agency responsible for managing the domestic nutrition assistance programs. Its mission is to increase food security and reduce hunger in partnership with cooperating organizations by providing children and low-income people access to food, a healthful diet and nutrition education in a manner that supports American agriculture and inspires public confidence. The domestic nutrition assistance programs include the Supplemental Nutrition Assistance Program (SNAP), the National School Lunch Program (NSLP), the School Breakfast Program (SBP), Special Supplemental Nutrition Program for Women, Infants and Children (WIC), Commodity Supplemental Food Program (CSFP), Food Distribution Program on Indian Reservations (FDPIR), the Emergency Food Assistance Program (TEFAP) and the Senior Farmers' Market Nutrition Program (SFMNP). Currently, the nutrition assistance programs managed by FNS touch the lives of 1 in 4 Americans over the course of a year.

Federal nutrition assistance programs operate as partnerships between FNS, State, Indian Tribal Organizations (ITOs) and local organizations that interact directly with program participants. States and ITOs voluntarily enter into agreements with the Federal Government to operate programs according to Federal standards in exchange for program funds that cover all benefit costs and a significant portion of administrative expenses. Under these agreements, FNS is responsible for implementing statutory requirements that set national program standards for eligibility and benefits, providing Federal funding to States, ITOs, and local partners and monitoring and evaluating program structures and policies to make sure they are properly implemented and effective in meeting program missions. States, ITOs and local organizations are responsible for delivering benefits efficiently, effectively and in a manner consistent with national requirements. States and ITOs may operate all or some of the 15 different domestic nutrition assistance programs.

FNS is consolidating certain programmatic and financial data reporting requirements that are currently approved by the Office of Management and Budget, under the Food Programs Reporting System (FPRS), an electronic reporting system. The purpose is to give States and ITO agencies one portal for the various reporting required for the programs that the States and ITOs operate. The data collected is used for a variety of purposes: mainly program evaluation, planning, audits, funding, research, regulatory compliance and general statistics.

Affected Public: State and Tribal Government.

Estimated Number of Respondents: 5,095.

Estimated Number of Responses per Respondent: 3.5.

Estimated Total Annual Responses: 18,047.

Estimated Time per Response: 4.8 hours. The average estimated time of response varies from .2–98 hours depending on respondent group and type of program report; therefore, FNS provided an estimate.

Estimated Total Annual Burden on Respondents: 86,811 hours.

Dated: March 27, 2013.

Audrey Rowe,

Administrator, Food and Nutrition Service.

[FR Doc. 2013–07956 Filed 4–4–13; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Agency Information Collection Activities: Proposed Collection: Comment Request: Supplemental Nutrition Assistance Program (SNAP) Education and Administrative Reporting System (EARS)

AGENCY: Food and Nutrition Service, USDA.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on a proposed information collection. The proposed collection is an extension, without change, of a currently approved collection. The purpose of the Education and Administrative Reporting System (EARS) form is to collect uniform and standard information on nutrition education activities (SNAP-Ed) funded by SNAP. The data collected will inform management decisions, support policy initiatives and provide documentation for legislative, budget and other requests that support planning within the agency.

DATES: Written comments must be submitted on or before June 4, 2013.

ADDRESSES: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions that were 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.

Comments may be sent to Jane Duffield, Chief, State Administration Branch, Program Accountability and Administration Division, Supplemental Nutrition Assistance Program, U.S. Department of Agriculture, Food and Nutrition Service, 3101 Park Center Drive, Room 818, Alexandria, VA 22302. Comments may also be submitted via fax to the attention of Jane Duffield at 703–605–0795, Room 824, or via email to *SNAP-Ed@fns.usda.gov*. Comments will also be accepted through the Federal eRulemaking Portal. Go to *http://www.regulations.gov* and follow the online instructions for submitting comments electronically.

All written comments will be open for public inspection at the office of the Food and Nutrition Service during regular business hours (8:30 a.m. to 5 p.m. Monday through Friday) at 3101 Park Center Drive, Room 824, Alexandria, Virginia 22302.

All responses to this notice will be summarized and included in the request for the Office of Management and Budget (OMB) approval. All comments will also be a matter of public record.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the proposed information collection form and instructions should be directed to Usha Kalro at 703–305–2397.

SUPPLEMENTARY INFORMATION:

Title: Education and Administrative Reporting System.

OMB Number: 0584–0542.

Form Number: FNS–759.

Expiration Date: 08/31/2013.

Type of Request: Extension, without change, of a currently approved collection.

Abstract: The Food and Nutrition Service (FNS) developed the Education and Administrative Reporting System (EARS) for the nutrition education (SNAP-Ed) component of the Supplemental Nutrition Assistance Program (SNAP), which is provided for in Section 11 of the Food and Nutrition Act 2008 (7 U.S.C. 2020 (f)(3)(B)(ii)). In 2003, the Agency convened a workgroup of diverse stakeholders to assist with this task, including people from the State, local and federal levels, as well as academia.

The EARS form was approved by OMB in Fiscal Year (FY) 2007. The first phase of EARS implementation, launched in FY 2008, required SNAP State agencies to report on financial questions #9 and #10 on the EARS form. Full implementation of all applicable EARS questions was required of SNAP State agencies by FY 2010. All State agencies fully complied with this requirement. EARS provides uniform data and information about the nutrition education activities of all participating States across the country. Data collected on the EARS form includes demographic characteristics of participants receiving nutrition education benefits, information about education topics and strategies and use of resources. The EARS form is designed as an annual report that SNAP State agencies submit using FNS web-based Food Program Reporting System (FPRS). FPRS is available to SNAP State agencies between October 15 and December 30 of each year for the submission of EARS data for the prior FY's nutrition education activities.

There are no changes in hourly burden since the last submission. FNS estimates that 52 State agencies will respond once a year for a total 52 annual responses. It will take approximately 54 burden hours for each State agency to respond for a total of 2,808 annual burden hours. There are no recordkeeping requirements imposed by this information collection.

Affected Public: Supplemental Nutrition Assistance Program (SNAP) State Agencies and implementing partners such as extension universities, non-profit organizations and local program operators.

Estimated Number of Respondents: 52.

Number of Responses per Respondent: 1.

Estimated Total Annual Responses: 52.

Hours per Response: 54.

Total Annual Burden Hours (Reporting Only): 2,808.

Dated: March 21, 2013.

Audrey Rowe,

Administrator, Food and Nutrition Service.

[FR Doc. 2013–07958 Filed 4–4–13; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Forest Service

Ochoco National Forest, Paulina Ranger District; Oregon; Wolf Creek Vegetation and Fuels Management Project EIS

AGENCY: Forest Service.

ACTION: Notice of Intent to Prepare an Environmental Impact Statement.

SUMMARY: The Ochoco National Forest is preparing an environmental impact statement (EIS) to analyze the effects of managing vegetation and fuels within the 24,506 acre Wolf project area, which is approximately 50 miles east of Prineville, Oregon. The project area includes National Forest system lands within the Lower Beavercreek watershed. The alternatives that will be analyzed include the proposed action, no action, and additional alternatives that will respond to issues generated through the scoping process. The Ochoco National Forest will give notice of the full environmental analysis and decision making process so interested and affected people may participate and contribute to the final decision.

DATES: Scoping comments must be received by May 20, 2013. The draft environmental impact statement is expected to be completed and available for public comment in October, 2013. The final environmental impact statement is expected to be completed in March, 2014.

ADDRESSES: Send written comments to Sandra Henning, District Ranger, Paulina Ranger District, Ochoco National Forest, 3160 NE Third Street, Prineville, Oregon 97754. Alternately, electronic comments may be sent to *comments-pacificnorthwest-ochoco@fs.fed.us.* Electronic comments must be submitted as part of the actual email message, or as an attachment in plain text (.txt), Microsoft Word (.doc), rich text format (.rtf), or portable document format (.pdf).

FOR FURTHER INFORMATION CONTACT: Jeffrey Marszal, Project Leader at 3160 NE Third Street, Prineville, Oregon 97754, or at (541) 416–6500, or by email *at jmarszal@fs.fed.us*

SUPPLEMENTARY INFORMATION:

Purpose and Need for Action

The existing condition of the Wolf planning area was evaluated in 2012 and documented in the Wolf Creek Watershed Analysis. The watershed analysis determined that conditions in the planning area have departed from the historic conditions in several ways.

- Tree species compositions are outside the historic range of variability.
- A reduction in Late and Old Structured forest (LOS); especially single-strata LOS.
- A reduction in open-canopy stands accompanied by an increase in stand densities and multi-storied stands.
- An increased risk of large-scale loss of forest to wildfire.
- An increased risk of insect infestation and/or disease that can impact forested stands.
- A decline in riparian/aquatic conditions and hardwood communities.

Based upon direction from the Ochoco Forest Plan and recommendations identified in the Wolf Creek WA, the Paulina Ranger District has determined that within the Wolf project area:

1. There is a need to manage vegetation towards to the historic range of variability to provide a range of forest conditions and habitats that would support historic disturbance processes, native wildlife, and plant species.
2. There is a need to reduce forest vegetation density and fuel loadings to reduce the risk that disturbance events such as insect, disease and wildfire will lead to a loss of desired forest conditions.
3. There is a need to increase or maintain large tree structure; especially single-strata LOS and maintain and increase the abundance of early-seral and fire tolerant species.
4. There is a need to improve riparian conditions and associated upland vegetation within Riparian Habitat Conservation Area (RHCAs) and maintain and enhance hardwood communities.
5. There is a need to contribute to the local and regional economies by providing timber and other wood fiber products now and in the future.

Proposed Action

The proposed action includes a variety of management strategies and activities, including commercial thinning with follow-up noncommercial thinning and/or slashes treatment (4,927 acres), noncommercial treatment with slash treatment (907 acres), juniper cutting with slash treatment (481 acres), underburning (4,910 acres) and hardwood enhancement (78 acres). Implementation of the proposed action would require some connected actions; these include use of temporary roads on existing disturbance (18 miles), use of new temporary roads (2 miles), stream restoration (1 location), material source expansion (1 location, 3 acres), and headcut repair (3 locations). Implementation of the proposed action would require the following mitigation to reduce or eliminate unwanted effects; these include road closure (2 miles) and road decommission (2.7 miles).

Responsible Official

The responsible official will be Kate Klein, Forest Supervisor, Ochoco National Forest, 3160 NE Third Street, Prineville, Oregon 97754.

Nature of Decision To Be Made

Given the purpose and need, the deciding official will review the proposed action, the other alternatives, and the environmental consequences in order to determine whether and under what circumstances vegetation and fuels management will be implemented in the Wolf Creek project area.

Preliminary Issues

The project's interdisciplinary team has developed a list of preliminary issues that will be used during the analysis of effects. Other issues may arise as a result of public comment and further analysis. Preliminary issues include:

- *Invasive Plant Species (Noxious Weeds).* Several populations of noxious weeds are known to exist within the project area. There is a risk that management activities may exacerbate the weed situation by spreading existing populations or introducing new ones.
- *Peck's Mariposa Lily.* Management activities can improve habitat for this sensitive species, but there is also risk of impacting individual plants and/or habitat where it occurs in the project area.
- *Soil Productivity.* Maintenance of soil productivity is an important objective for management of National Forest Lands. When mechanized equipment is used in the Forest, soil can become displaced and compacted, which can impact productivity.
- *Water Quality.* The main streams in the project area, Wolf, North Wolf and East Wolf Creeks, are listed on Oregon DEQ's 303(d) list due to high summer temperatures. Management activities can result in reduced shade on streams, as well as contribute sediment into the streams, which impacts water quality and decreases habitat quality for fish and other riparian fauna.
- *Wildlife Habitat.* Activities intended to improve forest health and resiliency may reduce habitat effectiveness for some wildlife species, including forest raptors and big game.

Scoping Process

The notice of intent initiates the scoping process, which guides the development of the environmental impact statement. It is important that reviewers provide their comments at such times and in such a manner that they are useful to the agency's preparation of the environmental impact statement. Therefore, comments should be provided prior to the close of the comments period and should clearly articulate the reviewer's concerns and contentions. Comments received in response to this solicitation including names and addresses of those who comment, will be part of the public record for this proposed action. Comments submitted anonymously will be accepted and considered.

Dated: April 1, 2013.

Sandra Henning,

District Ranger.

[FR Doc. 2013–07938 Filed 4–4–13; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF COMMERCE

International Trade Administration

Application(s) for Duty-Free Entry of Scientific Instruments

Pursuant to Section 6(c) of the Educational, Scientific and Cultural Materials Importation Act of 1966 (Pub.

L. 89–651, as amended by Pub. L. 106–36; 80 Stat. 897; 15 CFR part 301), we invite comments on the question of whether instruments of equivalent scientific value, for the purposes for which the instruments shown below are intended to be used, are being manufactured in the United States.

Comments must comply with 15 CFR 301.5(a)(3) and (4) of the regulations and be postmarked on or before April 25, 2013. Address written comments to Statutory Import Programs Staff, Room 3720, U.S. Department of Commerce, Washington, DC 20230. Applications may be examined between 8:30 a.m. and 5:00 p.m. at the U.S. Department of Commerce in Room 3720.

Docket Number: 13–007. Applicant: University of Illinois, Materials Research Lab, 104 S Goodwin Ave., Urbana, IL 61801. *Instrument:* Electron Microscope. *Manufacturer:* FEI Company, Czech Republic. *Intended Use:* The instrument will be used to seek the measurement and potentially direct-tailoring of materials properties, through the study of the relation of structure to catalytic activity, strain and composition within nanostructures, the effects of impurities on the strength of materials, and other properties of catalytic materials such as Pt, Ru, and Mo, semiconductor nanostructures (Si, Ge, InAs), metal alloys such as Ni/Al, and other materials. *Justification for Duty-Free Entry:* There are no instruments of the same general category manufactured in the United States. *Application accepted by Commissioner of Customs:* February 27, 2013.

Docket Number: 13–010. *Applicant:* University of Pittsburgh, 3700 O'Hara St., 636 Benedum Hall, Pittsburgh, PA 15261. *Instrument:* Electron Microscope. *Manufacturer:* FEI, Czech Republic. *Intended Use:* The instrument will be used to gain a better understanding of the relationship between microstructure and the performance of materials, through the analysis of crystallographic texture, the identification of crystallographic orientation relationships between precipitates and the matrix, precipitate size distributions and the analysis of chemical compositions of electronic materials, advanced ceramics for medical applications, advanced Ni-based Superalloys, stainless steels (for energy applications), advanced high-strength steels, and many other materials. *Justification for Duty-Free Entry:* There are no instruments of the same general category manufactured in the United States. *Application accepted by Commissioner of Customs:* March 4, 2013.

Docket Number: 13–011. *Applicant:* National Institutes of Health, Porter Neurosciences Research Center, 35 Covent Dr., Bethesda, MD 20892. *Instrument:* Electron Microscope. *Manufacturer:* JEOL Ltd., Japan. *Intended Use:* The instrument will be used to help understand how the human body functions normally, such as in learning, memory or hearing, and to understand the pathologies of human diseases. In order to understand these functions, this instrument will be used in experiments such as identifying the molecular components of a structure in an adult and in development, as well as looking for changes in the structure brought on by disease or by normal functional changes in cells of living organisms such as nerve cells or neurons of the brain, as well as inner ear cells. *Justification for Duty-Free Entry:* There are no instruments of the same general category manufactured in the United States. *Application accepted by Commissioner of Customs:* March 8, 2013.

Dated: March 28, 2013.

Gregory W. Campbell,

Director of Subsidies Enforcement, Import Administration.

[FR Doc. 2013–08024 Filed 4–4–13; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–966]

Drill Pipe From the People's Republic of China: Preliminary Results of Countervailing Duty Administrative Review; 2011

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) is conducting an administrative review of the countervailing duty (CVD) order on drill pipe from the People's Republic of China (PRC). The period of review (POR) is March 3, 2011, through December 31, 2011. We preliminary determine that Shanxi Yida Special Steel Imp. & Exp. Co., Ltd. and its cross-owned affiliates received countervailable subsidies during the POR.

DATES: *Effective Date:* April 5, 2013.

FOR FURTHER INFORMATION CONTACT: Kristen Johnson, AD/CVD Operations, Office 8, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone (202) 482–4793.

Scope of the Order

The scope of the order consists of steel drill pipe and steel drill collars, whether or not conforming to American Petroleum Institute (API) or non-API specifications. The merchandise subject to the order is currently classifiable under the Harmonized Tariff Schedule of the United States (HTSUS) categories: 7304.22.0030, 7304.22.0045, 7304.22.0060, 7304.23.3000, 7304.23.6030, 7304.23.6045, 7304.23.6060, 8431.43.8040 and may also enter under 8431.43.8060, 8431.43.4000, 7304.39.0028, 7304.39.0032, 7304.39.0036, 7304.39.0040, 7304.39.0044, 7304.39.0048, 7304.39.0052, 7304.39.0056, 7304.49.0015, 7304.49.0060, 7304.59.8020, 7304.59.8025, 7304.59.8030, 7304.59.8035, 7304.59.8040, 7304.59.8045, 7304.59.8050, and 7304.59.8055. Although the HTSUS subheadings are provided for convenience and customs purposes, the written product description, available in *Drill Pipe From the People's Republic of China: Countervailing Duty Order,* 76 FR 11758 (March 3, 2011) (*CVD Order*), remains dispositive.

A full description of the scope of the order is contained in the memorandum from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations to Paul Piquado, Assistant Secretary for Import Administration, ''Decision Memorandum for Preliminary Results of Countervailing Duty Administrative Review: Drill Pipe from the People's Republic of China'' (Preliminary Decision Memorandum), dated currently with this notice, and hereby adopted by this notice.

The Preliminary Decision Memorandum is a public document and is on file electronically via Import Administration's Antidumping and Countervailing Duty Centralized Electronic Service System (IA ACCESS). IA ACCESS is available to registered users at *http://iaaccess.trade.gov* and in the Central Records Unit, room 7046 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly on the Internet at *http://www.trade.gov/ia/*. The signed Preliminary Decision Memorandum and the electronic versions of the Preliminary Decision Memorandum are identical in content.

Methodology

The Department has conducted this review in accordance with section 751(a)(1)(A) of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found countervailable, we preliminarily determine that there is a subsidy, *i.e.,* a government-provided financial contribution that gives rise to a benefit to the recipient, and that the subsidy is specific. *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

In making these findings, we have relied, in part, on facts available and, because the Government of the PRC did not act to the best of its ability to respond to the Department's requests for information, we have drawn an adverse inference in selecting from among the facts otherwise available. *See* sections 776(a) and (b) of the Act. For further information, see ''Use of Facts Otherwise Available and Adverse Inferences'' in the Preliminary Determination Memorandum.

For a full description of the methodology underlying the Department's conclusions, *see* Preliminary Decision Memorandum.

Preliminary Results of the Review

As a result of this review, we preliminarily determine a net countervailable subsidy rate of 5.23 percent *ad valorem* for Shanxi Yida Special Steel Imp. & Exp. Co., Ltd. and its cross-owned affiliates Shanxi Yida Special Steel Group Co., Ltd. and Shanxi Yida Petroleum Equipment Manufacturing Co., Ltd., for the period March 3, 2011, through December 31, 2011.

Disclosure and Public Comment

The Department will disclose to parties to this proceeding the calculations performed in reaching the preliminary results within five days of the date of publication of these preliminary results.[1] Interested parties may submit written arguments (case briefs) within 30 days of publication of the preliminary results and rebuttal comments (rebuttal briefs) within five days after the time limit for filing the case briefs.[2] Pursuant to 19 CFR 351.309(d)(2), rebuttal briefs must be limited to issues raised in the case briefs. Parties who submit arguments are requested to submit with the argument: (1) 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, U.S. Department of Commerce within 30 days after the date of publication of this notice.[3] Requests should contain the party's name, address, and telephone number, the number of participants, and a list of the issues to be discussed. If a request for a hearing is made, we will inform parties of the scheduled date for the hearing, which will be held at the U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230, at a time and location to be determined.[4] Parties should confirm by telephone the date, time, and location of the hearing.

Parties are reminded that briefs and hearing requests are to be filed electronically using IA ACCESS and that electronically filed documents must be received successfully in their entirety by 5:00 p.m. Eastern Time on the due date.

Unless the deadline is extended pursuant to section 751(a)(3)(A) of the Act, the Department will issue the final results of this administrative review, including the results of our analysis of the issues raised by parties in their comments, within 120 days after issuance of these preliminary results.

Assessment Rates

Upon issuance of the final results, the Department shall determine, and U.S. Customs and Border Protection (CBP) shall assess, countervailing duties on all appropriate entries covered by this review. We intend to issue instructions to CBP 15 days after publication of the final results of this review.

Cash Deposit Instructions

The Department also intends to instruct CBP to collect cash deposits of estimated countervailing duties in the amounts shown above. For all non-reviewed firms, we will instruct CBP to collect cash deposits of estimated countervailing duties at the most recent company-specific or all-others rate applicable to the company. These cash deposit requirements, when imposed, shall remain in effect until further notice.

This administrative review and notice are in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.213.

Dated: April 1, 2013.

Paul Piquado,

Assistant Secretary for Import Administration.

Appendix I

List of Topics Discussed in the Preliminary Decision Memorandum:

1. Summary.
2. Background.
3. Scope of the Order.
4. Use of Facts Otherwise Available and Adverse Inferences.
5. Subsidy Valuation Information.
6. Loan Benchmark Rates.
7. Analysis of Programs.
8. Conclusion.

[FR Doc. 2013–08023 Filed 4–4–13; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See* 19 CFR 351.224(b).

[2] *See* 19 CFR 351.309(c)(1)(ii) and 351.309(d)(1).

[3] *See* 19 CFR 351.310(c).

[4] *See* 19 CFR 351.310.

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC607

Western Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of public meetings.

SUMMARY: The Western Pacific Fishery Management Council (Council) will hold meeting of its Pelagics Plan Team (PPT) and Archipelagic Fishery Ecosystem Plan Teams, in Honolulu, HI, to discuss fishery issues and develop recommendations for future management.

DATES: The meeting of the PPT will be held between April 23 and 24, 2013, from 8:30 a.m. to 5 p.m., and the Archipelagic Fishery Ecosystem Plan Teams will be held between April 22 and April 25, 2012, 8:30 a.m. to 5 p.m.

ADDRESSES: The meetings will be held at the Council Office Conference Room, Western Pacific Fishery Management Council, 1164 Bishop St., Suite 1400, Honolulu, HI 96813; telephone: (808) 522–8220.

FOR FURTHER INFORMATION CONTACT: Kitty M. Simonds, Executive Director; telephone: (808) 522–8220.

SUPPLEMENTARY INFORMATION: *The PPT will meet at the Council Pelagics Conference Room to discuss the following agenda items:*

Tuesday, April 23, 2013, 8.30 a.m.

1. Introduction
2. Annual Report
   a. Review 2012 Annual Report

modules and recommendations
i. Commonwealth of the Northern Mariana Islands (CNMI)
ii. American Samoa
iii. Guam
iv. Hawaii
v. International
vi. Recreational
b. 2012 Annual Report region wide recommendations

Wednesday, April 24, 2013, 8.30 a.m.

3. Ninth Regular Session of the Western and Central Pacific Fishery Commission
4. South Pacific albacore and American Samoa longline costs earnings study
5. North Pacific striped marlin
6. Pacific bluefin tuna
7. Cook Islands/Forum Fisheries Agency sub-regional office in Pago Pago
8. Update on false killer whale Take Reduction Plan
9. Biological opinion for deep set tuna fishery
10. Outstanding Fishery Ecosystem Plan amendments
11. Other business
12. Public comment
13. Pelagic Plan Team Recommendations

The Hawaii and Pacific Remote Island Areas (PRIAS) Archipelago Fishery Ecosystem Plan Team Meeting will meet at the Council's Conference Room to discuss the following agenda items:

Tuesday, April 22, 2013, 8:30 a.m.

1. Welcome and Introductions
2. Approval of the Agenda
3. Assignment of Rapporteurs
4. Status of Fishery Monitoring Programs and Research Projects
A. Coral Reef Fisheries
B. Crustacean Fisheries
C. Precious Coral Fisheries
D. Bottomfish Fisheries
i. Main Hawaiian Islands (MHI) Annual Catch Target (ACT) Monitoring
ii. Market Delay Amendment
E. National Marine Fisheries Service (NMFS) Pacific Islands Regional Office (PIRO PIRO Administrative Activities
F. Discussions
5. Improving Annual Catch Limit (ACL) specifications and stock assessments
A. Recalculation of gold coral Maximum Sustainable Yield (MSY)
B. New black coral research to support ACL re-specification
C. Discussions
6. Data collection and reporting issues
A. Recreational fishing updates
B. Update on Omnibus Data Collection Improvement Proposal
C. Discussions
7. Review of the Council Five-Year Research Priorities
8. Update Cooperative Research and developing priorities
9. General Discussions
10. Other Business
11. Public Comment
12. Hawaii and PRIA Archipelago Plan Team recommendations

The Joint American Samoa and Marianas Archipelago Fishery Ecosystem Plan Team will meet at the Council's Conference Room to discuss the following agenda items:

Wednesday–Thursday, April 23–24, 2013, 8:30 a.m.–5 p.m.

13. Welcome and Introductions
14. Approval of the Agenda
15. Assignment of Rapporteurs
16. Report on previous Plan Team recommendations and Council actions
17. Review of the Status of the Western Pacific Insular Fisheries
A. Commonwealth of Northern Mariana Islands
i. Coral reef fisheries
ii. Bottomfish fisheries
iii. Potential use of Bio-Sampling data to improve fishery data
iv. Update of fishery dependent and independent studies
v. Administrative and regulatory updates
vi. Discussions
B. Guam
i. Coral reef fisheries
ii. Bottomfish fisheries
iii. Potential use of Bio-Sampling data to improve fishery data
iv. Update of fishery dependent and independent studies
v. Administrative and regulatory updates
vi. Discussions
C. American Samoa
i. Coral reef and crustacean fisheries
ii. Bottomfish fisheries
iii. Potential use of Bio-Sampling data to improve fishery
iv. Update of fishery dependent and independent studies
v. Administrative and regulatory updates
vi. Discussions
18. Review of the Council Five-Year Research Priorities
19. Update of Cooperative Research and Developing Priorities and Projects
20. General Discussions
21. Other Business
22. Public Comment
23. Annual Catch Limits
A. Evaluating 2012 catches relative to its respective ACLs
B. Using model based approaches to determine MSY and depletion-corrected average catches for Acceptable Biological Catch (ABC) specification
C. Discussions
24. Improving Fishery Data Collection in the Western Pacific Region
A. Update on Status of Fishery Data Collection Improvement Actions
B. Data collection in military installations in Guam
C. Update on the status of the Omnibus Fishery Data Collection Improvement Proposal
D. Using Bio-Sampling data to enhance creel surveys
25. Protected Species
A. Update on the Endangered Species Act (ESA) Petitioned Species
i. Pacific humphead wrasse
ii. Eight species of coral reef fish
26. Other Business
27. Public Comments
28. Rapporteur reports
29. General discussions and Plan Team recommendations

Plan Team Training: A Brief Introduction to Length-Based Mortality Assessment for Coral Reef Fishes

30. Length-based stock assessment approach: pros and cons, some examples from Florida, Caribbean, and Hawaii.
31. Age and growth of tropical boney fishes. Age at length relationship (e.g., von Bertalanffy). Fitting growth curves. Allometric (Weight-Length) growth.
32. Mortality rates and abundance estimation. Development of exponential mortality model, average population size, and population biomass models. Assessing life span, maximum age and natural mortality, size-age of first capture, selectivity.
33. Integrating the parts. Model development and assessing exploitation rates via average size in the exploited phase of the population.
34. Fisheries-independent and fisheries-dependent surveys to obtain average length in the exploited phase.
35. Computer Laboratory—Estimating mortality rates using a length-based mortality model in Excel.

The order in which the agenda items are addressed April change. The PPT will meet as late as necessary to complete scheduled business.

Although non-emergency issues not contained in this agenda April come before the PPT for discussion, those issues April not be the subject of formal action during these meetings. Plan Team action will be restricted to those issues specifically listed in this document and

any issue arising after publication of this document that requires emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Councils intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kitty M. Simonds, (808) 522–8220 (voice) or (808) 522–8226 (fax), at least 5 days prior to the meeting date.

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

Dated: April 2, 2013.

William D. Chappell,

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

[FR Doc. 2013–07954 Filed 4–4–13; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0649–XC608

New England Fishery Management Council; Public Meeting

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

ACTION: Notice of a public meeting.

SUMMARY: The New England Fishery Management Council (Council) will hold a three-day meeting on to consider actions affecting New England fisheries in the exclusive economic zone (EEZ).

DATES: The meeting will be held on Tuesday, Wednesday and Thursday, April 23–25, 2013 starting at 9 a.m. on Tuesday, and at 8:30 a.m. on both Wednesday and Thursday.

ADDRESSES: The meeting will be held at the Hilton Hotel, 20 Coogan Blvd., Mystic, CT 06355–1900; telephone: (860) 572–0731; fax: (860) 572–0328; or online at *www.hiltonmystic.com.*

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950; telephone: (978) 465–0492.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Tuesday, April 23, 2013

The New England Council will hold a closed session on Tuesday from 9 a.m. to 10 a.m. to address appointments to its Scientific and Statistical Committee. Following the closed session, the Chairman will make any necessary introductions and announcements. The Council will then receive brief reports from the NEFMC Chairman and Executive Director, NOAA Fisheries Regional Administrator, the Northeast Fisheries Science Center and Mid-Atlantic Fishery Management Council liaisons, as well as NOAA General Counsel, and representatives of the Atlantic States Marine Fisheries Commission, Coast Guard, and staff from NOAA Enforcement/VMS. The Council also will receive an update about Northeast Regional Ocean Council activities. Prior to the lunch break, an open period for public comments is scheduled during which any interested party may provide brief remarks on issues relevant to Council business but not listed on the meeting agenda.

During the afternoon session the Council will receive a report from the Northeast Fisheries Science Center staff summarizing the findings of the 56th Stock Assessment Workshop/Stock Assessment Review Committee meetings. The species addressed were surf calms and ocean quahogs and white hake. The Transboundary Management Guidance Committee will brief the Council on its February intersessional meeting held to discuss quota trading, assessment timing, alternative management strategies and the U.S./Canada Resource Sharing Understanding. The Groundfish Committee report will follow and include: an update on the development of Amendment 18 to the Northeast Multispecies Fishery Management Plan (FMP); a presentation by the Northeast Fisheries Science Center's Social Sciences Branch on its fishing year 2011 Groundfish Report; and a discussion about cod catch reporting in the Eastern Georges Bank Area.

Wednesday, April 24, 2013

The Council will begin its second day of meetings with a brief update on recent recommendations concerning habitat management areas, dedicated habitat research areas, and the inclusion of gear modification measures in the Omnibus Habitat Amendment 2. Following this report, the Council will continue to address groundfish management issues as it discusses recent correspondence that requests a review of the impacts of climate change on groundfish status determination criteria and catch advice and any follow up action. Additionally, Council members will consider Groundfish Committee recommendations for new alternatives in Omnibus Habitat Amendment 2 that would improve conservation of juvenile groundfish habitat and protect concentrations of large spawning groundfish. These new area alternatives could replace some or all of the status quo year-round groundfish closed areas and rolling closures. After the April Council meeting, the groundfish management alternatives will be consolidated and possibly combined with the existing habitat and dedicated habitat research areas that have been proposed by the Habitat Committee.

Thursday, April 25, 2013

The NEFMC's Monkfish Committee will review the development of Amendment 6 to the Monkfish Fishery Management Plan (FMP). This report also will include a review of the April 2013 update assessment. Under this agenda item the Council also may discuss the ability of NOAA Fisheries to provide data that adequately supports a monkfish sector or ITQ program. The Scallop Committee will initiate Framework Adjustment 25 to the Atlantic Sea Scallop FMP (specifications for fishing year 2014 and default measures for 2015). The action will include accountability measures for windowpane flounder, among other issues. The Council also will approve priorities for inclusion in the upcoming scallop research set-aside program announcement that will detail future funding opportunities for sea scallop-related research. The Enforcement Committee will review recommendations for possible approval concerning sector managers and joint liability; gear marking requirements across all FMPs; small, seasonal closed areas; and allowing vessels to simultaneously carry nets with different mesh sizes for different fisheries in the regulated mesh areas. Prior to a lunch break, the NOAA Fisheries Northeast Regional Office will present a Draft Environmental Assessment on Standard Bycatch Reporting Methodology and seek approval to finalize proposals for public review. The day will conclude with an initial discussion about Magnuson-Stevens Act reauthorization priorities.

Although other non-emergency issues not contained in this agenda may come before this Council for discussion, those issues may not be the subjects of formal action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any

issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided that the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Paul J. Howard (see **ADDRESSES**) at least 5 days prior to the meeting date.

Dated: April 2, 2013.

William D. Chappell,

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

[FR Doc. 2013–07979 Filed 4–4–13; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Telecommunications and Information Administration

First Responder Network Authority Board Meeting

AGENCY: National Telecommunications and Information Administration, U.S. Department of Commerce.

ACTION: Notice of Open Public Meeting.

SUMMARY: The National Telecommunications and Information Administration (NTIA) will convene an open public meeting of the Board of the First Responder Network Authority (FirstNet).

DATES: The meeting will be held on June 4, 2013, from 8:30 a.m. to 11:30 a.m. Mountain Daylight Time.

ADDRESSES: Board members will meet in the Cotton II Room at the Westin Westminster Hotel, 10600 Westminster Boulevard, Westminster, Colorado, 80020.

FOR FURTHER INFORMATION CONTACT: Uzoma Onyeije, Secretary, FirstNet, National Telecommunications and Information Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230: telephone (202) 482–0016; email *uzoma@firstnet.gov.* Please direct media inquiries to NTIA's Office of Public Affairs, (202) 482–7002.

SUPPLEMENTARY INFORMATION:

This notice informs the public that the FirstNet Board has scheduled a meeting on June 4, 2013, in Westminster, Colorado.[1] The June 4 Board meeting will be held in conjunction with the Public Safety Communications Research Program (PSCR) 2013 Public Safety Broadband Stakeholder Conference, organized to discuss public safety's opportunities and challenges associated with deployment of the nationwide public safety broadband network. For information on the conference, please visit *http://www.pscr.gov/about_pscr/highlights/psbb_062013/psbb_june_2013_stakeholder_mtg_info.php*

Background: The Middle Class Tax Relief and Job Creation Act of 2012 (Act), Public Law 112–96, 126 Stat. 156 (2012), created the First Responder Network Authority (FirstNet) as an independent authority within the National Telecommunications and Information Administration (NTIA). The Act directs FirstNet to establish a single nationwide, interoperable public safety broadband network. The FirstNet Board is responsible for making strategic decisions regarding FirstNet's operations. The FirstNet Board held its first public meeting on September 25, 2012.

Matters To Be Considered: NTIA will post a detailed agenda on its Web site, *http://www.ntia.doc.gov,* prior to the meeting on June 4, 2013. The agenda topics are subject to change. The Board may, by a majority vote, close a portion of the meeting as necessary to preserve the confidentiality of commercial or financial information that is privileged or confidential, to discuss personnel matters, or to discuss legal matters affecting FirstNet, including pending or potential litigation. *See* 47 U.S.C. 1424(e)(2).

Time and Date: The meeting will be held on June 4, 2013, from 8:30 a.m. to 11:30 a.m. Mountain Daylight Time. The time is subject to change.

Place: Board members will meet in the Cotton II Room at the Westin Westminster Hotel, 10600 Westminster Boulevard, Westminster, Colorado 80020.

Other Information: The meeting is open to the public and press. Given the space limitations of the meeting room, members of the public wishing to attend the meeting in person will be directed to the Westminster Ballroom at the Westin Westminster Hotel, 10600 Westminster Boulevard, Westminster, Colorado 80020, where they can observe the meeting by video.

The meeting is accessible to people with disabilities. Individuals requiring accommodations, such as sign language interpretation or other ancillary aids, are asked to notify Uzoma Onyeije, Secretary, FirstNet, at (202) 482–0016 or *uzoma@firstnet.gov* at least five (5) business days before the meeting.

The meeting will also be webcast. Please refer to NTIA's Web site at *http://www.ntia.doc.gov/category/firstnet* for webcast instructions and other information. If you have technical questions regarding the webcast, please contact Charles Franz at *cfranz@ntia.doc.gov.* Access details for these meetings are subject to change. Please refer to NTIA's Web site at *http://www.ntia.doc.gov/category/firstnet* for the most current information.

Records: NTIA maintains records of all Board proceedings. Board minutes will be available at *http://www.ntia.doc.gov/category/firstnet.*

Dated: April 1, 2013.

Kathy D. Smith,

Chief Counsel.

[FR Doc. 2013–07877 Filed 4–4–13; 8:45 am]

BILLING CODE 3510–60–P

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Customer Account Registration and Maintenance

ACTION: Proposed collection; comment request.

SUMMARY: The United States Patent and Trademark Office (USPTO), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on this new information collection, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before June 4, 2013.

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

- *Email: InformationCollection@uspto.gov.* Include ''0651–00xx Customer Account Registration and Maintenance'' in the subject line of the message.
- *Mail:* Susan K. Fawcett, Records Officer, Office of the Chief Information Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.
- *Federal Rulemaking Portal: http://www.regulations.gov.*

[1] On November 9, 2012, NTIA published a notice in the **Federal Register** noting that a public meeting of the FirstNet Board would be held on June 11, 2013, in San Francisco, California, and that NTIA would publish a future notice for this meeting. 77 FR 67342 (Nov. 9, 2012). This notice provides an update to correct the date, time, and location information for the Board's June 2013 meeting.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Susan K. Fawcett, Records Officer, Office of the Chief Information Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450; by telephone at 571–272–5429; or by email to *Susan.Fawcet@uspto.gov.* Additional information about this collection is also available at *http://www.reginfo.gov* under ''Information Collection Review.''

SUPPLEMENTARY INFORMATION:

I. Abstract

The United States Patent and Trademark Office (USPTO) seeks to launch ''MyUSPTO,'' an optional customer portal that will serve as a central point for access to online system interfaces and submission of information to the USPTO. Customers will have the opportunity to create online accounts through USPTO.gov that will collect information for a variety of programmatic purposes. MyUSPTO will initially serve as an authoritative source for customer contact and correspondence information (such as current addresses, official email addresses, and telephone numbers) and will eventually allow customers to create a portfolio of information that can be retained and used for other business transactions with the USPTO. In the future, MyUSPTO will also provide a unified interface with convenient access to other USPTO systems, such as electronic fee payments.

With MyUSPTO, the agency seeks to establish the option for customers to obtain a single login that can be used to access USPTO's online systems, reducing the need to maintain multiple user names for different activities or re-enter information such as correspondence addresses for every authorized transaction.

Guidance from the Office of Management and Budget (OMB) memorandum ''Social Media, Web-Based Interactive Technologies, and the Paperwork Reduction Act'' dated April 7, 2010, states that self-identifying information for the creation of user accounts or profiles is not subject to the Paperwork Reduction Act (PRA) under certain conditions. However, the PRA does apply ''when agencies use online accounts to collect information for programmatic purposes.'' Since the customer accounts will provide an option for users to submit information for programmatic purposes, the USPTO is seeking approval to collect this information under the PRA. This new collection is expected to enhance but not influence any existing or future information requirements for business before the Office.

II. Method of Collection

Electronic.

III. Data

OMB Number: 0651–00xx.

Form Number(s): None.

Type of Review: New collection.

Affected Public: Individuals or households; businesses or other for-profits; and not-for-profit institutions.

Estimated Number of Respondents: 10,000 responses per year. The USPTO estimates that approximately 20% of these responses will be from small entities.

Estimated Time Per Response: The USPTO estimates that it will take the public from 2 to 12 minutes (0.03 to 0.20 hours) to gather, prepare, and submit the information required for this collection.

Estimated Total Annual Respondent Burden Hours: 1,150 hours.

Estimated Total Annual Respondent Cost Burden: $283,475. The USPTO expects that the information in this collection will be prepared by attorneys and paraprofessionals. Using the estimate hourly rates of $371 for attorneys and $122 for paraprofessionals, the USPTO expects that the average hourly rate for respondents to this collection will be $246.50. Therefore, the USPTO estimates that the total respondent cost burden for submitting the information in this collection will be approximately $283,475 per year.

Item	Estimated time for response	Estimated annual responses	Estimated annual burden hours
Customer Profile Account Request and Maintenance	12 minutes	5,000	1,000
Correspondence and Contact Information	2 minutes	5,000	150
Totals		10,000	1,150

Estimated Total Annual Non-hour Respondent Cost Burden: $0. There are no capital start-up, maintenance, or recordkeeping costs associated with this information collection. There are no fees for setting up a customer profile. All transactions will be received and processed electronically.

IV. Request for Comments

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record.

The USPTO is soliciting public comments to:

(a) 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; (b) 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; (c) Enhance the quality, utility, and clarity of the information to be collected; and (d) 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.

Dated: April 2, 2013.

Susan K. Fawcett,

Records Officer, USPTO, Office of the Chief Information Officer.

[FR Doc. 2013–07933 Filed 4–4–13; 8:45 am]

BILLING CODE 3510–16–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions to and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to and Deletions from the Procurement List.

SUMMARY: This action adds products and services to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes products and services from the Procurement List previously furnished by such agencies.

DATES: *Effective Date:* 5/6/2013.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 Clark Street, Suite 10800, Arlington, Virginia 22202–4149.

FOR FURTHER INFORMATION CONTACT: Barry S. Lineback, Telephone: (703) 603–7740, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION:

Additions

On 2/1/2013 (78 FR 7412–7413) and 2/8/2013 (78 FR 9386–9387), the Committee for Purchase From People Who Are Blind or Severely Disabled published notices of proposed additions to the Procurement List.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the products and services and impact of the additions on the current or most recent contractors, the Committee has determined that the products and services listed below are suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the products and services to the Government.

2. The action will result in authorizing small entities to furnish the products and services to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the products and services proposed for addition to the Procurement List.

End of Certification

Accordingly, the following products and services are added to the Procurement List:

Products

NSN: MR 1153—Basket, Cooking, Steel, Multipurpose
NSN: MR 1159—Set, Bakeware, Cake Pop
NPA: Industries for the Blind, Inc., West Allis, WI
Contracting Activity: DEFENSE COMMISSARY AGENCY, FORT LEE, VA
Coverage: C-List for the requirements of military commissaries and exchanges as aggregated by the Defense Commissary Agency.

NSN: 7025–00–NIB–0004—Mouse, Optical Sensor, Black and Grey, Ergonomic shaped
NPA: L.C. Industries for the Blind, Inc., Durham, NC
Contracting Activity: GENERAL SERVICES ADMINISTRATION, NEW YORK, NY
Coverage: A-List for the Total Government Requirement as aggregated by the General Services Administration.

NSN: 7510–00–NIB–9843—Self Stick Rectangular Flag, .5'' x 1.7'', Multi Pack (Red/yellow/blue/green)
NPA: Association for the Blind and Visually Impaired—Goodwill Industries of Greater Rochester, Rochester, NY
Contracting Activity: GENERAL SERVICES ADMINISTRATION, NEW YORK, NY
Coverage: A-List for the Total Government Requirement as aggregated by the General Services Administration.

Services

Service Type/Location: Custodial/Janitorial Service, Cochiti Lake Project Office, 82 Dam Crest Road, Pena Blanca, NM
NPA: Adelante Development Center, Inc., Albuquerque, NM
Contracting Activity: DEPT OF THE ARMY, W075 ENDIST ALBUQUERQUE, ALBUQUERQUE, NM

Service Type/Location: Custodial Service, Toulson Courthouse, 129 East Main Street, Salisbury, MD
NPA: Worcester County Developmental Center, Newark, MD
Contracting Activity: PUBLIC BUILDINGS SERVICE, GSA/PBS/R03 SOUTH SERVICE CENTER, PHILADELPHIA, PA

Deletions

On 3/23/2012 (77 FR 17035), 4/27/2012 (77 FR 25146–25147), 5/11/2012 (77 FR 27737), 5/25/2012 (77 FR 31335–31336), 6/29/2012 (77 FR 38775–38776), 8/3/2012 (77 FR 46411), 10/5/2012 (77 FR 60969), 10/12/2012 (77 FR 62219–62220), 10/26/2012 (77 FR 65365), 11/2/2012 (77 FR 66181), 11/16/2012 (77 FR 68737–68738), 12/7/2012 (77 FR 73025–73026), 1/18/2013 (78 FR 4133–4134), 2/8/2013 (78 FR 9386–9387), and 2/15/2013 (78 FR 11159), the Committee for Purchase From People Who Are Blind or Severely Disabled published notices of proposed deletions from the Procurement List.

After consideration of the relevant matter presented, the Committee has determined that the products and services listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action may result in authorizing small entities to furnish the products and services to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the products and services deleted from the Procurement List.

End of Certification

Accordingly, the following products and services are deleted from the Procurement List:

Products

NSN: 7530–00–238–4316—Card, Index
NSN: 7530–01–037–5556—Paper, Mimeograph and Duplicating
NPA: Louisiana Association for the Blind, Shreveport, LA
Contracting Activity: GENERAL SERVICES ADMINISTRATION, NEW YORK, NY

NSN: 7520–01–585–0981—Calendar, Wall, Monthly Undated/Yearly Dated
NPA: The Chicago Lighthouse for People Who Are Blind or Visually Impaired, Chicago, IL
Contracting Activity: GENERAL SERVICES ADMINISTRATION, FSS HOUSEHOLD AND INDUSTRIAL FURNITURE, ARLINGTON, VA

Shredders

NSN: 7490–01–567–4337—Fellowes Model 4000CC
NSN: 7490–01–567–4338—Fellowes Model 4000SC
NSN: 7490–01–567–4339—Fellowes Model 970CC
NPA: L.C. Industries for the Blind, Inc., Durham, NC
Contracting Activity: GENERAL SERVICES ADMINISTRATION, NEW YORK, NY

NSN: 8345–00–260–2724—Flag, Signal, Vehicle, Danger Red
NPA: There was no other nonprofit agency authorized to furnish the products.
Contracting Activity: DEFENSE LOGISTICS AGENCY TROOP SUPPORT, PHILADELPHIA, PA

Envelope, Wallet

NSN: 7530–00–NIB–0260
NSN: 7530–00–NIB–0261
NSN: 7530–00–NIB–0262

NPA: There was no other nonprofit agency authorized to furnish the products.
Contracting Activity: NATL GEOSPATIAL-INTELLIGENCE AGENCY, BETHESDA, MD

Binder, Loose-leaf, 3-Ring

NSN: 7510–01–484–1760
NSN: 7510–01–484–1752
NSN: 7510–01–484–1750
NSN: 7510–01–484–1751
NSN: 7510–01–484–1748
NSN: 7510–01–484–1749
NPA: South Texas Lighthouse for the Blind, Corpus Christi, TX
Contracting Activity: GENERAL SERVICES ADMINISTRATION, NEW YORK, NY

NSN: 7045–01–599–9345—USB Flash Drive, 256-Bit AES Encryption, Level 3 Encrypted, Anti-Virus, 4GB
NSN: 7045–01–599–9346—USB Flash Drive, 256-Bit AES Encryption, Level 3 Encrypted, Anti-Virus, 32GB
NSN: 7045–01–599–9348—USB Flash Drive, 256-Bit AES Encryption, Level 3 Encrypted, Anti-Virus, 8GB
NSN: 7045–01–599–9352—USB Flash Drive, 256-Bit AES Encryption, Level 3 Encrypted, 2GB
NSN: 7045–01–599–9354—USB Flash Drive, 256-Bit AES Encryption, Level 3 Encrypted, Anti-Virus, 2GB
NSN: 7045–01–599–9353—USB Flash Drive, 256-Bit AES Encryption, Level 3 Encrypted, Anti-Virus, 16GB
NSN: 7045–01–568–9694—USB 2.0 Hard Drive, Portable, 320G
NPA: North Central Sight Services, Inc., Williamsport, PA
Contracting Activity: GENERAL SERVICES ADMINISTRATION, NEW YORK, NY

NSN: 7420–01–484–1758—Clipboard w/ Calculator
NPA: MidWest Enterprises for the Blind, Inc., Kalamazoo, MI
Contracting Activity: GENERAL SERVICES ADMINISTRATION, NEW YORK, NY

Bag, Sleeping, Firefighter's

NSN: 8465–00–081–0798
NPAs: Blind Industries & Services of Maryland, Baltimore, MD
RLCB, Raleigh, NC
Contracting Activity: GENERAL SERVICES ADMINISTRATION, FORT WORTH, TX

Glove Powder Free, Encore Hydrasoft

NSN: 6515–00–NIB–0445
NSN: 6515–00–NIB–0446
NSN: 6515–00–NIB–0447
NSN: 6515–00–NIB–0448
NSN: 6515–00–NIB–0449
NSN: 6515–00–NIB–0450
NSN: 6515–00–NIB–0451
NSN: 6515–00–NIB–0452
NPA: Bosma Industries for the Blind, Inc., Indianapolis, IN
Contracting Activity: DEPARTMENT OF VETERANS AFFAIRS, NAC, HINES, IL

NSN: 9905–00–565–6268—Sign Kit, Replacement
NPA: CW Resources, Inc., New Britain, CT
Contracting Activity: GENERAL SERVICES ADMINISTRATION, FORT WORTH, TX

NSN: 8465–00–860–0256—Cover, Water Canteen
NPA: Human Technologies Corporation, Utica, NY
Contracting Activity: DEFENSE LOGISTICS AGENCY TROOP SUPPORT, PHILADELPHIA, PA

Mat, Floor Rubber

NSN: 2540–01–298–8449—61'' x 36'' fabricated mat, reinforced with steel wire
NPA: Hope Haven, Inc., Rock Valley, IA
Contracting Activity: DEFENSE LOGISTICS AGENCY LAND AND MARITIME, COLUMBUS, OH

SKILCRAFT-Spartan chemical cleaners

NSN: 8125–00–NIB–0032—Spray Bottle, Tb-Cide Plus II Disinfectant
NSN: 7930–00–NIB–0578—GreenSolutions High Dilution 256 Neutral Disinfect
NSN: 7930–00–NIB–0579—Tb-Cide Plus II Disinfectant
NSN: 7930–00–NIB–0597—Tb-Cide Quat RTU Disinfectant
NPA: Susquehanna Association for the Blind and Vision Impaired, Lancaster, PA
Contracting Activity: DEPARTMENT OF VETERANS AFFAIRS, NAC, HINES, IL

NSN: 8465–01–524–2765—Hydramax Hydration System, ALPHA Reflector, Orange Reflective Tape
NPA: The Lighthouse for the Blind, Inc. (Seattle Lighthouse), Seattle, WA
Contracting Activity: GENERAL SERVICES ADMINISTRATION, FORT WORTH, TX
NSN: 7520–01–584–1378—Pen & Calculator Case, Rosewood
NPA: Tarrant County Association for the Blind, Fort Worth, TX
Contracting Activity: GENERAL SERVICES ADMINISTRATION, NEW YORK, NY

NSN: 8115–00–NIB–0001—Container, Mailing Cassette
NSN: 8115–00–NIB–0003—Cassette, Mailing Container
NPA: L.C. Industries for the Blind, Inc., Durham, NC
Contracting Activity: LIBRARY OF CONGRESS, WASHINGTON DC

Cloth, Abrasive, Aluminum-oxide, 50 Grit, Drill Back, Grey, 50 Yard

NSN: 5350–00–187–6275—1''
NSN: 5350–00–187–6297—2''
NPA: Louisiana Association for the Blind, Shreveport, LA
Contracting Activity: GENERAL SERVICES ADMINISTRATION, FORT WORTH, TX

NSN: 7520–01–510–7490—Pen, Retractable, Cushion Grip, Gel Ink, Dignitary
NSN: 7520–01–510–7491—Pen, Retractable, Cushion Grip, Gel Ink, Dignitary
NSN: 7510–01–510–7493—Refill, Dignitary Gel Ink Pen
NSN: 7510–01–510–8416—Refill, Dignitary Gel Ink Pen
NPA: Industries of the Blind, Inc., Greensboro, NC
Contracting Activity: GENERAL SERVICES ADMINISTRATION, NEW YORK, NY

Services

Service Type/Location: Janitorial/Ground Maintenance Service, U.S. Army Reserve Center: Mt. View, Mt. View, CA
NPA: Social Vocational Services, Inc., San Jose, CA
Contracting Activity: DEPT OF THE ARMY, W40M NATL REGION CONTRACT OFC, FORT BELVOIR, VA

Service Type/Location: Sorting of Time & Attendance Reports Service, Department of Transportation, 1777 Phoenix Parkway Building, College Park, GA
NPA: WORKTEC, Jonesboro, GA
Contracting Activity: DEPARTMENT OF TRANSPORTATION, SAINT LAWRENCE SEAWAY DEVELOPMENT CORP., MASSENA, NY

Service Type/Location: Mailroom Operation Service, U.S. Army Reserve Command, Atlanta, GA
NPA: WORKTEC, Jonesboro, GA
Contracting Activity: DEPT OF THE ARMY, W6QM MICC CTR–FT SAM HOUSTON, FORT SAM HOUSTON, TX

Service Type/Location: Janitorial/Custodial Service, Defense Logistics Agency: Point Pleasant Depot, Defense National Stockpile Zone, 2601 Madison Avenue, Point Pleasant, WV
NPA: Prestera Center for Mental Health Services, Inc., Huntington, WV
Contracting Activity: DEFENSE LOGISTICS AGENCY SUPPORT SERVICES—DSS, FORT BELVOIR, VA

Service Type/Location: Facilities Maintenance Service, Yakima Training Center and Multipurpose Range Complex, Multipurpose Training Range, Yakima, WA
NPA: Skookum Educational Programs, Bremerton, WA
Contracting Activity: DEPARTMENT OF THE ARMY, W6QM FT LEWIS, DIRECTORATE OF CONTRACTING, FORT LEWIS, WA

Barry S. Lineback,

Director, Business Operations.

[FR Doc. 2013–07986 Filed 4–4–13; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List, Proposed Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed Additions to and Deletions from the Procurement List.

SUMMARY: The Committee is proposing to add products to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and delete services previously provided by such agencies.

Comments Must Be Received On or Before: 5/6/2013.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S. Clarke Street, Suite 10800, Arlington, Virginia 22202–4149.

For Further Information or To Submit Comments Contact: Barry S. Lineback, Telephone: (703) 603–7740, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Additions

If the Committee approves the proposed additions, the entity of the Federal Government identified in this notice will be required to procure the products listed below from the nonprofit agency employing persons who are blind or have other severe disabilities.

The following products are proposed for addition to the Procurement List for production by the nonprofit agency listed:

Products

Gloves, Mechanics, Men's and Women's, Black

NSN: 8415–01–497–5381—small
NSN: 8415–01–497–5384—medium
NSN: 8415–01–497–5989—large
NSN: 8415–01–497–5987—xlarge
NSN: 8415–01–501–1557—xxlarge
NPA: South Texas Lighthouse for the Blind, Corpus Christi, TX
Contracting Activity: GENERAL SERVICES ADMINISTRATION, FORT WORTH, TX
Coverage: B-List for the Broad Government Requirement as aggregated by the General Services Administration.

Deletions

The following services are proposed for deletion from the Procurement List:

Services

Service Type/Location: Document Processing Service, Bureau of Alcohol, Tobacco, Firearms & Explosives, National Training Center, 244 Needy Road, Martinsburg, WV
NPA: Jeanne Bussard Center, Inc., Frederick, MD
Contracting Activity: DEPARTMENT OF THE TREASURY, WASHINGTON, DC

Service Type/Location: Janitorial/Custodial Service, U.S. Army Reserve Center: Wilkes-Barre, 1001 Highway 315, Wilkes-Barre, PA
NPA: United Rehabilitation Services, Inc., Wilkes-Barre, PA
Contracting Activity: DEPT OF THE ARMY, W6QM MICC–FT DIX (RC–E), FORT DIX, NJ

Barry S. Lineback,

Director, Business Operations.

[FR Doc. 2013–07985 Filed 4–4–13; 8:45 am]

BILLING CODE 6353–01–P

DEPARTMENT OF DEFENSE

Department of the Army

Environmental Impact Statement for Modernization and Repair of Piers 2 and 3, Military Ocean Terminal Concord, CA

AGENCY: Department of the Army, DoD.

ACTION: Notice of Intent.

SUMMARY: The Department of the Army announces its intent to conduct public scoping under the National Environmental Policy Act to gather information to prepare an Environmental Impact Statement (EIS) related to the critically-needed modernization and repairs of Piers 2 and 3, Military Ocean Terminal Concord (MOTCO) due to structural decay caused by severe deterioration, wide-spread marine borer damage, and fungal decay. Piers 2 and 3 are used to transport military supplies in the Pacific region. There may be significant impacts to threatened and endangered species. The following other resource areas may be impacted: water quality, noise, terrestrial and marine species, and traffic. For example, the proposed action will replace a large number of piles; this work will likely result in water quality issues and an increase in noise. The Department of the Army will use the analysis in the EIS to determine whether and how to implement the proposed action.

ADDRESSES: Written comments should be forwarded to Mr. Malcolm Charles, Directorate of Public Works, Attention: SDAT–CCA–MI (Charles), 410 Norman Ave, Concord, CA 94520; email: *usarmy.motco.sddc.mbx.list-eis@mail.mil* or fax (925) 246–4171.

FOR FURTHER INFORMATION CONTACT: Please contact Mr. Malcolm Charles, Directorate of Public Works, 410 Norman Ave, Concord, CA 94520; fax (925) 246–4171; email: *usarmy.motco.sddc.mbx.list-eis@mail.mil.*

SUPPLEMENTARY INFORMATION: The decision to be made by the Army is whether and how to modernize and repair Piers 2 and 3 at the MOTCO. The EIS will assess the direct, indirect, and cumulative environmental impacts associated with various proposed facility modernization and repair options to meet safety, operational, facilities management, land use, and cultural resources management objectives.

Piers 2 and 3 at MOTCO need to be repaired and modernized in order to maintain ammunition out load capabilities at this ocean terminal. Pier 2 is the westernmost of three main wharves and is currently inoperable due to its poor condition. The pier requires major rehabilitation and modernization in order to restore its function and bring it to current containerization standards. The deterioration is due to a combination of marine borer, fungal decay, and overloading.

Pier 3 is currently the primary operational wharf at MOTCO. While it is in fair condition overall, it has localized areas of severe deterioration, wide-spread marine borer damage, and fungal decay. Consequently, work at the pier is subject to loading restrictions, and recent engineering assessments estimate that it has approximately five years of practical service life remaining.

The proposed action consists of the modernization and repair of the critically-needed piers. A range of reasonable alternatives, including a No Action Alternative, will be developed and analyzed in the EIS. Alternatives to be considered include (1) Fully implement repairs to Piers 2 and 3 with Pier 2 re-oriented to align/rotate the west end to meet a more modernized configuration, (2) fully implement repairs to Piers 2 and 3 leaving the Pier 2 footprint in its present location, and (3) fully implement repairs to Piers 2 and 3, reorienting Pier 2 to meet a more modernized configuration (same as in Alternative 1) but with a larger deck surface and heavier carrying capacity. Other reasonable alternatives raised during the scoping process and capable of meeting the project purpose and need and criteria will be considered for evaluation in the EIS.

Scoping and public comments: Federally recognized Tribes, federal, state, and local agencies, organizations, and the public are invited to be involved in the scoping process for the preparation of this EIS by participating in scoping meetings and/or submitting written comments. The scoping process will help identify possible alternatives, potential environmental impacts, and key issues of concern to be analyzed in the EIS. Written comments will be accepted within 60 days of publication of the NOI in the **Federal Register**. Scoping meetings will be held in Concord, CA. Notification of the times and locations for the scoping meetings will be locally published.

Brenda S. Bowen,

Army Federal Register Liaison Officer.

[FR Doc. 2013–07880 Filed 4–4–13; 8:45 am]

BILLING CODE 3710–08–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

[Docket Number DARS–2013–0011]

Information Collection Requirement; Defense Federal Acquisition Regulation Supplement (DFARS); Radio Frequency Identification Advance Shipment Notices

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Notice and request for comments regarding a proposed extension of an approved information collection requirement.

SUMMARY: In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), DoD announces the proposed extension of a public information collection requirement and seeks public comment on the provisions thereof. *DoD invites comments on:* (a) Whether the proposed collection of information is necessary for the proper performance of the functions of DoD, including whether the information will have practical utility; (b) the accuracy of the estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including the use of automated collection techniques or other forms of information technology. The Office of Management and Budget (OMB) has approved this information collection for use through August 31, 2013. DoD proposes that OMB extend its approval for use for three additional years beyond the current expiration date.

DATES: DoD will consider all comments received by June 4, 2013.

ADDRESSES: You may submit comments, identified by OMB Control Number 0704–0434, using any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Email: dfars@osd.mil. Include OMB Control Number 0704–0434 in the subject line of the message.

Fax: 571–372–6094.

Mail: Defense Acquisition Regulations System, Attn: Mr. Dustin Pitsch, OUSD(AT&L)DPAP(DARS), 3060 Defense Pentagon, Room 3B855, Washington, DC 20301–3060.

Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Mr. Dustin Pitsch, 571–372–6090. The information collection requirements addressed in this notice are available on the World Wide Web at: *http://www.acq.osd.mil/dpap/dars/dfarspgi/current/index.html.* Paper copies are available from Mr. Dustin Pitsch, OUSD(AT&L)DPAP(DARS), 3060 Defense Pentagon, Room 3B855, Washington, DC 20301–3060.

SUPPLEMENTARY INFORMATION:

Title, Associated Form, and OMB Number: Defense Federal Acquisition Regulation Supplement (DFARS), Part 211 and related clause at 252.211; Radio Frequency Identification Advance Shipment Notices, OMB Control Number 0704–0434.

Needs and Uses: DoD uses advance shipment notices for the shipment of material containing RFID tag data. DoD receiving personnel use the advance shipment notice to associate the unique identification encoded on the RFID tag with the corresponding shipment. Use of the RFID technology permits DoD an automated and sophisticated end-to-end supply chain, which has increased visibility of assets and permits delivery of supplies to the warfighter more quickly.

Affected Public: Businesses or other for-profit and not-for profit institutions.

Number of Respondents: 25,000.

Responses per Respondent: 3,981.

Annual Responses: 101,515,500.

Average Burden per Response: Approximately 1.1 seconds.

Annual Burden Hours: 31,556.

Frequency: On occasion.

Summary of Information Collection

The clause at DFARS 252.211–7006, Radio Frequency Identification Advance Shipment Notices, requires the contractor to ensure that the data on each passive RFID tag are unique and conforms to the requirements that they are readable and affixed to the appropriate location on the specific level of packaging in accordance with MIL–STD–129 tag placement specifications. The contractor shall encode an approved RFID tag using the appropriate instructions at the time of contract award. Regardless of the selected encoding scheme, the contractor is responsible for ensuring that each tag contains a globally unique identifier. The contractor shall electronically submit advance shipment notices with the RFID tag identification in advance of the shipment in accordance with the procedures at *https://wawf.eb.mil/.*

Kortnee Stewart,

Editor, Defense Acquisition Regulations System.

[FR Doc. 2013–07966 Filed 4–4–13; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

Notice of Intent To Prepare an Environmental Impact Statement and Conduct Scoping Meeting for the Berths 212–224 [YTI] Container Terminal Project at the Port of Los Angeles, Los Angeles County, California (SPL–2013–0113–TS)

AGENCY: U.S. Army Corps of Engineers, DoD.

ACTION: Notice of Intent.

Authority: 33 U.S.C. 403; 33 U.S.C. 1344; 33 U.S.C. 1413.

SUMMARY: The purpose of this notice is to initiate the scoping process for preparation of an Environmental Impact Statement (EIS) for the Los Angeles Harbor Department (LAHD) Berths 212–224 [YTI] Container Terminal Improvement Project.

DATES: Submit comments concerning this notice on or before May 6, 2013. A public scoping meeting will be held on April 23, 2013 at 6:00 p.m. (PST).

ADDRESSES: The scoping meeting location is: Los Angeles Harbor Department, Board of Harbor Commissioners Hearing Room, 425 S. Palos Verdes Street, San Pedro, CA 90731.

Mail written comments concerning this notice to: U.S. Army Corps of Engineers, Los Angeles District, Regulatory Division, Ventura Field Office, ATTN: SPL–2013–00113–TS, 2151 Alessandro Drive, Suite 110, Ventura, CA 93001. Comment letters should include the commenter's physical mailing address, the project title and the Corps file number in the subject line.

FOR FURTHER INFORMATION CONTACT: Theresa Stevens, Ph.D., U.S. Army Corps of Engineers, Los Angeles District, Regulatory Division, Ventura Field Office, ATTN: SPL–2013–00113–TS, 2151 Alessandro Drive, Suite 110, Ventura, CA 93001, (805) 585–2146, *theresa.stevens@usace.army.mil.*

SUPPLEMENTARY INFORMATION: In accordance with the National Environmental Policy Act (NEPA), the Corps is requiring the preparation of an

Environmental Impact Statement (EIS) prior to any permit action. The Corps may ultimately make a determination to permit or deny the proposed project or a modified version of the proposed project. The primary Federal concerns are dredging, dredged material disposal, addition of permanent structures in and over navigable waters of the U.S., and transport of dredged material for the purpose of ocean disposal.

Pursuant to the California Environmental Quality Act (CEQA) the LAHD will serve as Lead Agency in preparing an Environmental Impact Report (EIR) for its consideration of development approvals within its jurisdiction. The Corps and LAHD have agreed to jointly prepare a Draft EIS/EIR to optimize efficiency and avoid duplication. The Draft EIS/EIR is intended to be sufficient in scope to address the Federal, state and local requirements and environmental issues concerning the proposed activities and permit approvals.

1. *Project Site and Background Information.* The project site is located on Terminal Island within in an industrial area of the East Basin region of the Port of Los Angeles. The site is within the Port of Los Angeles Community Plan area in the City of Los Angeles, adjacent to the communities of San Pedro and Wilmington, and approximately 20 miles south of downtown Los Angeles. The purpose of the project is to improve marine shipping and maritime commerce by optimizing the container-handling efficiency and capacity at Berths 212–224, accommodate berthing and loading/unloading the largest container ships, and increase on-dock rail facilities to accommodate projected peak increases in container movement into and out of the terminal at Berths 212–224 resulting from the handling of larger ships.

2. *Proposed Action:* The LAHD has proposed to redevelop the existing container terminal at Berths 212–224. Yusen Terminals Inc. [YTI] operates the existing 185-acre container terminal under a lease agreement (LAHD Permit No. 692). The proposed project would result in dredging of approximately 25,000 cubic yards of sediment from Berths 212–224 to increase depth at existing berths; disposal of dredged material at either an offshore site (LA–2), confined disposal facility (CDF), or other approved location; wharf improvements including installation of new subsurface sheet pile and king piles to stabilize the existing wharf prior to dredging, installation of four new 100-gauge and modification (i.e., heightening, additional boom length) of six existing gantry cranes for a total of 14 operational cranes at full build-out; and backland improvements such as additional on-dock rail, paving, cold-planing, etc., on approximately 160 acres of the site.

3. *Issues:* Potentially significant issues associated with the project include: Aesthetics/visual impacts, air quality emissions, biological resource impacts, environmental justice, geologic impacts related to seismicity, hazards and hazardous materials, hydrology and water quality, noise, traffic and transportation, and cumulative impacts from past, present and reasonably foreseeable future projects.

4. *Alternatives.* The Draft EIS/EIR will include a co-equal analysis of several alternatives. Project alternatives will be further developed during this scoping process. Additional alternatives that may be developed during scoping will also be considered in the Draft EIS/EIR.

5. *Scoping Process.* The Corps and LAHD will jointly conduct a public scoping meeting for the proposed project to receive public comment regarding the appropriate scope and preparation of the Draft EIS/EIR. Participation by Federal, state, and local agencies and other interested organization and persons is encouraged. This meeting will be conducted in English and Spanish.

6. *Electronic Access and Filing Addresses:* Comments may be submitted by electronic mail (email) to: *theresa.stevens@usace.army.mil*. Electronic mail comments should include the commenter's physical or electronic mailing address, the project title and the Corps file number.

7. The Draft EIS/EIR is expected to be available for public review and comment in the fall 2013, and a public meeting will be held after its publication.

Dated: March 19, 2013.

David J. Castanon,

Chief, Regulatory Division.

[FR Doc. 2013–07968 Filed 4–4–13; 8:45 am]

BILLING CODE 3720–58–P

DEFENSE NUCLEAR FACILITIES SAFETY BOARD

Extension of Hearing Record Closure Date

AGENCY: Defense Nuclear Facilities Safety Board.

ACTION: Extension of hearing record closure date.

SUMMARY: The Defense Nuclear Facilities Safety Board (Board) published a document in the **Federal Register** on January 22, 2013, (78 FR 4393), as amended, February 19, 2013, (78 FR 11632). The publication concerned notice of a hearing and meeting on March 14, 2013, regarding safety culture, emergency preparedness, and safety issues at the Pantex Plant. The Board stated in the January 22, 2013, hearing notice that the hearing record would remain open until April 15, 2013, for the receipt of additional materials.

Extension of Time: The Board now extends the period of time for which the hearing record will remain open to June 15, 2013, to further accommodate, among other things, submission of answers to questions taken for the record during the course of the public hearing.

Contact Person for Further Information: Marcelyn Atwood, General Manager, Defense Nuclear Facilities Safety Board, 625 Indiana Avenue NW., Suite 700, Washington, DC 20004–2901, (800) 788–4016. This is a toll-free number.

Dated: April 2, 2013.

Peter S. Winokur,

Chairman.

[FR Doc. 2013–07969 Filed 4–4–13; 8:45 am]

BILLING CODE 3670–01–P

DEPARTMENT OF ENERGY

Spent Nuclear Fuel Management at the Savannah River Site

AGENCY: U.S. Department of Energy.

ACTION: Amended Record of Decision.

SUMMARY: The U.S. Department of Energy (DOE) is amending its August 7, 2000, Record of Decision (ROD) pursuant to the *Savannah River Site Spent Nuclear Fuel Management Final Environmental Impact Statement, Aiken, SC* (DOE/EIS–0279, 2000; SRS SNF EIS). In the 2000 ROD, DOE decided to develop and demonstrate the ''melt and dilute'' technology to manage approximately 28.6 metric tons of heavy metal (MTHM) of aluminum-clad SNF, consistent with its preferred alternative identified in the SRS SNF EIS.

DOE now amends that decision and will manage approximately 3.3 MTHM from the currently projected inventory of 22 MTHM at SRS using conventional processing [1] at the H-Canyon facility at SRS, as described and evaluated under the Conventional Processing Alternative

[1] Conventional processing is a chemical separations process that involves dissolving spent fuel in nitric acid and separating fission products from uranium using solvent extraction.

in the SRS SNF EIS. The quantity of 3.3 MTHM is the minimum amount of SNF necessary to avoid the need for costly modifications to the L-Basin that would allow DOE to accommodate expected receipts of SNF for the foreseeable future. This includes up to 200 High Flux Isotope Reactor (HFIR) cores generated at the Oak Ridge National Laboratory and approximately 1,000 bundles of aluminum-clad SNF currently stored at SRS, as well as target residue materials [2] containing enriched uranium (including target materials from Canada that contain liquid Highly Enriched Uranium (HEU) of U.S. origin). DOE anticipates that processing this SNF and target residue material would begin as early as 2014 and continue approximately four years. As a result of this amended decision, HEU in the SNF and target materials will be down-blended to low-enriched uranium (LEU). This end product will not be useable in nuclear weapons, but will be available for use in commercial power reactors such as those operated by the Tennessee Valley Authority (TVA) to generate electricity. DOE will continue to safely store the aluminum-clad SNF not addressed in this Amended ROD in L-Basin at SRS, pending future analysis and DOE decisions.

In accordance with DOE regulations for implementing the National Environmental Policy Act (NEPA), DOE has prepared a Supplement Analysis (SA) to examine previous NEPA analyses of the management of SNF at SRS, particularly the SRS SNF EIS and the *Proposed Nuclear Weapons Nonproliferation Policy Concerning Foreign Research Reactor Spent Nuclear Fuel Environmental Impact Statement* (DOE/EIS–0218, 1996, FRR EIS) tiered from the *Programmatic Spent Nuclear Fuel Management and Idaho National Engineering Laboratory Environmental Restoration and Waste Management Programs Final Environmental Impact Statement* (DOE/EIS–0203, 1995), to determine whether DOE's amended decision would make substantial changes in its proposed actions or whether there are significant new circumstances or information relevant to environmental concerns and bearing on the proposed action or its potential impacts. Based on the SA, DOE has determined that a supplemental or new EIS is not required.

[2] Target materials are residual materials left after the desired isotopes have been removed from the targets. For example, target materials could be residual materials from the production in a research reactor of molybdenum-99, which decays to technetium-99, a medical isotope. Targets may be shaped as plates, pins, or cylinders. Target materials are not high-level radioactive waste.

The actions to be taken pursuant to this Amended ROD strongly support U.S. non-proliferation policy and goals by permanently dispositioning HEU. In particular, this amended decision implements the U.S. and Canadian agreement reached at the Nuclear Security Summit in March 2012 to expand efforts to return U.S.-origin HEU currently stored in Canada to the U.S. The commitment supports international efforts to consolidate and dispose of HEU and to combat nuclear terrorism. The actions addressed in this amended decision will free existing storage space in L-Basin, avoiding the need and cost required to provide additional new space in the Basin. This in turn will allow for continued receipt of Foreign Research Reactor SNF (FRR SNF), adequate storage for HFIR cores, continued operation of HFIR in support of DOE's research and development mission, dispositioning of HEU out of South Carolina, and cost-effective use of DOE's H-Canyon processing facility at SRS.

ADDRESSES: This Amended ROD, the SA for SRS SNF Management, and related NEPA documents are available on the DOE NEPA Web site at *www.nepa.energy.gov* and the SRS Web site at *www.srs.gov/general/pubs/envbul/nepa/htm.* To request copies of these documents, please contact:

Mr. Andrew R. Grainger, NEPA Compliance Officer, Savannah River Operations Office, U.S. Department of Energy, P.O. Box B, Aiken, South Carolina 29802, Telephone: (803) 952–8001, Email: *drew.grainger@srs.gov.*

FOR FURTHER INFORMATION CONTACT: For further information on the management of SNF at SRS, please contact Mr. Grainger as listed above.

For information on DOE's NEPA process, please contact:

Ms. Carol M. Borgstrom, Director, Office of NEPA Policy and Compliance, GC–54, U.S. Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585, Telephone: (202) 586–4600, or leave a message at (800) 472–2756, Email: *askNEPA@hq.doe.gov.*

SUPPLEMENTARY INFORMATION:

Background

DOE's purpose and need for action, as described in the SRS SNF EIS, is to develop and implement a safe and efficient SNF management strategy that includes preparing aluminum-clad SNF and target material stored at SRS, or expected to be shipped to SRS, for ultimate disposition offsite.

In the SRS SNF EIS, DOE grouped the SNF to be managed based on characteristics such as fuel size, physical and chemical properties, and radionuclide inventory. The fuel groups and the seven technologies that could be used to prepare the SNF for disposition are described in the SRS SNF EIS. The potential environmental impacts associated with the use of these technologies, including conventional processing, were analyzed in the SRS SNF EIS. In the ROD for the SRS SNF EIS (65 FR 48224; August 7, 2000), DOE identified the Minimum Impact Alternative as the environmentally preferable alternative, but selected the Preferred Alternative.[3]

To implement the Preferred Alternative described in the SRS SNF EIS, DOE decided to use a combination of technologies, including melt and dilute, to manage the SNF. The melt and dilute technology was to be used to treat all Group B fuel (about 20 MTHM of Material Test Reactor fuel from foreign and domestic reactors), all Group C fuel (about 8 MTHM of oxide and silicide foreign and domestic reactor fuel) except failed fuel (which DOE would treat by conventional processing), and most Group D materials (about 0.6 MTHM of foreign research reactor targets). DOE estimated that these fuels and target materials would total approximately 28.6 MTHM, based on quantities then stored at SRS and estimated quantities located at domestic and foreign reactor locations scheduled or eligible to ship fuel to SRS.[4] These shipments began in 1996 and are continuing. DOE now estimates that there are approximately 22 MTHM of SNF and target material at or eligible to be sent to SRS. This is less than the 28.6 MTHM evaluated in the SRS SNF EIS because DOE now expects to receive less FRR SNF than originally estimated.

The FRR EIS evaluated alternatives for return to the United States of SNF and target materials containing HEU enriched in the United States and supplied to foreign countries. Return of HEU for safe storage and disposition

[3] DOE developed five alternatives that could be used to manage SNF: No Action; Minimum Impact; Direct Disposal; Maximum Impact; and the Preferred Alternative; these alternatives and the fuel groups are described in the SRS SNF EIS and summarized in the 2000 ROD.

[4] On June 1, 1995, DOE announced that, among other actions, aluminum-clad SNF would be consolidated at SRS for management and non-aluminum-clad SNF would be consolidated at the Idaho National Laboratory (INL) (60 FR 28680; June 1, 1995). In keeping with this decision, when DOE announced its decision to implement a new foreign research reactor spent fuel acceptance policy, DOE stated that aluminum-clad fuel would be shipped to SRS and non-aluminum-clad fuel would be shipped to the INL (61 FR 25092; May 17, 1996).

advances the United States nuclear material nonproliferation goals. Appendix B1.5 of the FRR EIS discusses the two methods for preparing the target residue materials for transport: calcining and oxidizing. In the FRR EIS, DOE assumed that target residue material would be transported in solid form, and DOE evaluated the impacts of transportation accordingly. In Appendix B.2.1.2 of the FRR EIS, DOE explained that foreign research reactor shipments would be carried out in accordance with regulations set by the Department of Transportation (49 CFR parts 171 through 178) and the Nuclear Regulatory Commission (NRC) (10 CFR part 71); those regulations remain in place. In the FRR ROD, DOE decided, consistent with the programmatic decision to consolidate storage by fuel type, to transport to and store aluminum-clad SNF and target material at the SRS.

Supplement Analysis

In accordance with DOE NEPA regulations at 10 CFR 1021.314, DOE prepared an SA for the SRS SNF EIS and the FRR EIS (DOE/EIS–0279–SA–01 and DOE/EIS–0218–SA–06, March 2013) to consider a proposal to process the minimum quantity of SNF necessary to avoid the need for costly modifications to the L-Basin that would allow DOE to accommodate expected receipts of SNF for the foreseeable future. To do this, DOE estimated that processing approximately 1000 bundles of SNF and up to 200 HFIR cores currently stored at SRS would provide the minimum necessary amount of storage space. This could be accomplished over approximately a four-year period and equates to approximately 3.3 MTHM of the currently projected 22 MTHM total inventory. DOE would continue to safely store the remaining SNF in L-Basin at SRS, pending future analysis and DOE decisions. DOE also evaluated plans to receive FRR target residue material from Canada in accordance with U.S. acceptance policy and consistent with U.S. nonproliferation objectives. The target material, containing U.S.-origin HEU in liquid form, would be shipped in Type B casks certified by NRC.

The SA compared the proposal to the relevant NEPA reviews to determine whether the proposal would make substantial changes in the proposed actions identified in the SRS SNF EIS or FRR EIS, or whether there are significant new circumstances or information relevant to environmental concerns and bearing on the proposed action or its impacts, consistent with the Council on Environmental Quality NEPA implementing regulations at 40 CFR Parts 1502.9. DOE analyzed the use of conventional processing for SNF in lieu of the melt and dilute technology, which was never developed due to technical issues involving the off-gas system and funding limitations. The conventional processing approach is consistent with U.S. nuclear non-proliferation goals in that HEU would be eliminated and plutonium present in the SNF would not be separated from the fission products. Processing of the approximately 3.3 MTHM of SNF and target residue materials in H-Canyon will result in plutonium-bearing high-level waste (HLW) that will be vitrified in the Defense Waste Processing Facility (DWPF) at SRS, creating up to approximately 24 canisters of vitrified, proliferation-resistant HLW. This increase is not significant in the context of the approximately 7,000 canisters DOE estimates will be otherwise produced by the DWPF, and is within the DWPF production and SRS planned storage capabilities.

In the SA, DOE evaluated the addition of a third dissolver in H-Canyon to return the dissolving capacity for SNF to the level supported by H-Canyon's off-gas system and processing capability,[5] which are the capacities evaluated in the SRS SNF EIS. Installation and operation of a third dissolver in H-Canyon will take place entirely within H-Canyon and will not result in any land disturbance. Construction waste generated will be managed using existing SRS facilities and procedures. Operation of a third dissolver is within H-Canyon's dissolving capacity for SNF and is supported by existing systems, e.g., off-gas system. DOE would continue to use one existing dissolver to process plutonium material; plutonium dissolution does not require use of the off-gas treatment system or H-Canyon's solvent extraction capacity and raffinate systems. The air and liquid releases and other impacts of operating two dissolvers and the associated systems to process SNF would not significantly differ from those reported in the SRS SNF EIS, because the evaluation of the potential environmental impacts associated with conventional processing assumed the use of two dissolvers.

In the SA, DOE also evaluated the transportation, receipt, and processing of target residue materials in liquid form (from Canada) rather than solid form and found that the potential environmental impacts would not significantly differ from results presented in the FRR EIS and the SRS SNF EIS. For this analysis, DOE assumed that the NRC would certify use of an existing Type-B cask for the target residue materials. NRC consideration of the certification request is ongoing. Based on conclusions reached in the SA, DOE determined that the preparation of a supplemental or new EIS is not required.

Amended Decision

DOE has decided to manage up to 200 HFIR cores, approximately 1,000 bundles of SNF, and target residue materials containing HEU (including target residue materials containing liquid HEU from Canada) using conventional processing in H-Canyon at SRS. This SNF and these target residue materials, totaling approximately 3.3 MTHM, include material from Groups B, C, and D identified in the SRS SNF EIS. HEU recovered during conventional processing will be down-blended to create LEU feedstock for fuel fabrication for commercial nuclear reactors. The shipments of target residue materials in liquid form from Canada will comply with all applicable transportation regulations in both countries to ensure environmental protection and the safety of the involved workers and the general public. No target material or waste from processing target material will be returned to Canada. DOE will implement minor modifications to H-Canyon to receive liquid HEU as described in the SA.

DOE anticipates processing these materials beginning as early as 2014 and continuing approximately four years, consistent with program and policy priorities. DOE will install a third dissolver in H-Canyon in addition to two existing dissolvers, in order to cost-effectively utilize H-Canyon, and expeditiously complete the mission.

The aluminum-clad SNF not addressed in this amended ROD will remain safely in wet storage in L-Basin at SRS, pending future analysis and DOE decisions. The water chemistry will continue to be rigorously controlled to prevent any corrosion reactions between the storage tubes, fuel, and the basin water.

No environmental impacts resulting from operations under this amended decision would require specific mitigation measures. DOE will continue its current practices and policies to use all practicable means to avoid or minimize environmental harm and

[5] One H-Canyon dissolver currently supports dissolution of plutonium metal, preparatory to oxidizing it in the HB-Line to prepare plutonium oxide feed material for the Mixed Oxide Fuel Fabrication Facility (see Interim Action Determination, Use of H-Canyon/HB-Line to Prepare Feed for Mixed Oxide Fuel Fabrication Facility at the Savannah River Site, June 2012).

impacts to workers when implementing the actions described herein. For example, DOE will continue to evaluate and implement, as appropriate, physical modifications to the H-Canyon facility and process chemistry changes that would reduce personnel exposure, facility effluents, and waste generation.

Basis for Decision

This amended decision reduces the overall cost of managing the currently stored fuel by eliminating the need for additional SNF storage racks in the L-Basin SNF storage facility and allows for future receipt of foreign and domestic SNF, including continued receipt of HFIR cores from the Oak Ridge National Laboratory in support of DOE's research and development mission. In addition, this amended decision will maximize near-term utilization of H-Canyon and expeditiously complete the mission

This amended decision supports DOE's ongoing approach for reducing the proliferation risks inherent in stocks of HEU by down-blending surplus HEU to LEU. The LEU would be available for use in commercial reactors such as those operated by TVA. In addition, operation of H-Canyon to process the SNF is consistent with section 3137 of the Floyd D. Spence Defense Authorization Act for fiscal year (FY) 2001 (Pub. L. 106–398), as amended by section 3115 of the National Defense Authorization Act for FY 2004 (Pub. L. 108–136), regarding the continued operation and maintenance of a high state of readiness of the H-Canyon facility at SRS.

Given the expense involved in designing and constructing a new melt and dilute capability, and because an alternative processing technology (conventional processing) is readily available, DOE determined that melt and dilute is an unnecessarily costly duplication of treatment capability for aluminum-clad SNF. Conventional processing and down-blending the HEU to LEU, with vitrification rather than the recovery of plutonium, furthers the Nation's non-proliferation goals.

Although the Secretary of Energy has determined that Yucca Mountain is not a workable option for a geologic repository, DOE remains committed to meeting its obligations to safely dispose of SNF and HLW.[6] While this Amended ROD will increase the number of canisters of vitrified HLW, this is not expected to significantly affect the quantity of vitrified HLW requiring management.

Separately, the receipt of target residue materials from Canada in liquid form under the U.S. Foreign Research Reactor Acceptance Policy does not present significant new health or environmental concerns or impacts as described in the SA. The repatriation of U.S.-origin HEU from Canada will help ensure national and international safety and security by downblending this material to LEU that would be available for beneficial use in power reactors. This action is consistent with U.S. agreements regarding receipt of FRR materials in which involved countries with the economic ability to do so contribute to the costs of transportation and U.S. receipt, processing and disposition of the materials.

In summary, the proposed use of conventional processing for a limited quantity of SNF as described in this amendment to DOE's 2000 SNF ROD takes advantage of existing processes in existing facilities. It will allow near-term progress in processing a portion of the inventory analyzed in the SRS SNF EIS currently stored on the site, thus freeing storage space for expected material receipts and avoiding the cost of creating additional space. The activities encompassed by this amended decision will not incur potential health or environmental impacts significantly different from those analyzed in existing NEPA reviews. These activities will strongly contribute to DOE's commitment to the United States' nuclear non-proliferation goals and are consistent with the U.S. and Canadian agreement reached at the Nuclear Security Summit in March 2012 to expand efforts to return U.S.-origin HEU currently stored in Canada to the U.S. Further, the actions resulting from this Amended ROD will contribute to the production of material that can be put to beneficial energy production for public use, thereby dispositioning some HEU out of South Carolina; and will contribute to an overall safe, secure, and cost-effective strategy for ongoing management of SNF and target residue materials at SRS.

Issued in Washington, DC on March 29, 2013.

David Huizenga,

Senior Advisor for Environmental Management.

[FR Doc. 2013–07994 Filed 4–4–13; 8:45 am]

BILLING CODE 6450–01–P

[6] The Secretary's *Strategy for the Management and Disposal of Used Nuclear Fuel and High-level Radioactive Waste,* January 2013, endorses the key principles of the 2012 Blue Ribbon Commission on America's Nuclear Future report and represents an initial basis for discussions among the Administration, the Congress, and other stakeholders toward a sustainable path forward for disposition of nuclear waste.

DEPARTMENT OF ENERGY

Office of Energy Efficiency and Renewable Energy

Wireless Metering Challenge

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

ACTION: Notice of availability; request for comments.

SUMMARY: The U.S. Department of Energy (DOE) Office of Energy Efficiency and Renewable Energy (EERE) requests comments on the draft version of the *Wireless Power Meter Challenge Specification.* This draft is a set of performance specifications applicable to energy efficiency metering devices for use at the electrical panel level within commercial buildings. The specifications are intended to spur the development of new technologies in the wireless electric metering space.

DATES: Comments on the *Wireless Meter Challenge Specification* must be received by 5 p.m. Eastern Standard Time April 26, 2013.

DOE will be holding a webinar on April 30, 2013. Information regarding the webinar is provided in the **SUPPLEMENTARY INFORMATION** section.

ADDRESSES: Comments may be submitted by electronic mail to *wireless.meter@ee.doe.gov*.

For further information on how to submit comments, please see the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: For questions regarding the submission of comments, technical questions, and questions regarding the Challenge, contact Jason Koman, Building Technologies Office, Mailstop EE–2J, Office of Energy Efficiency and Renewable Energy, U.S. Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585. Phone number: (202) 287–1578. Email: *Jason.Koman@ee.doe.gov*.

For legal questions contact Christopher Calamita, U.S. Department of Energy, Office of the General Counsel, Forrestal Building, GC–71, 1000 Independence Avenue SW., Washington, DC 20585. Phone number: (202) 586–1777. Email: *christopher.calamita@hq.doe.gov*.

SUPPLEMENTARY INFORMATION: EERE is developing a challenge specification to spur the development of new, low cost wireless electric metering devices. In order to take action to reduce energy usage, owners and operators need to know how energy is being used in their buildings. Metering data provides

visibility to a building's energy use. Energy costs can be reduced by taking action to resolve problems identified by examining metered data. While metering systems do not directly improve energy efficiency, metering systems enable focused energy efficiency actions. It is estimated that the use of metering systems result in energy efficiency actions that deliver electricity energy savings of at least 2% or more annually. Today, the cost of building and panel level metering systems is typically a key hurdle to implementing these technologies.

Through the *Wireless Power Meter Challenge,* EERE is developing an aspirational but achievable performance specification for wireless metering devices at a low price point. The intent is to identify performance specifications that would meet the demand from the commercial building sector and leverage this demand to spur manufacturers to create new technologies. This model has been successfully deployed in the past through EERE's Roof Top Unit Challenge (RTU) in which DOE provided a similar performance specification that had not yet been offered on the market and manufacturers responded with compliant technologies, resulting in the most efficient products available on the market.

The *Wireless Power Meter Challenge Specification* is supported by the Building Technologies Office (BTO) Commercial Building Integration (CBI) team. In developing the draft *Specification,* EERE has considered input from Federal Agencies and individual comments from commercial building owners. This will be the first time EERE has issued a notice requesting general public comment on the *Specification.*

EERE is providing an opportunity for public comment on the technical provisions laid out in the *Specification.* EERE may give further consideration to certain technical elements and subsequently make changes to the *Specification* as a result of issues identified by commenters. The draft *Specification* is available at *http://www1.eere.energy.gov/buildings/commercial/bba_wireless metering.html.*

DOE intends to host a webinar on April 30, 2013, to provide information on the development of the *Specification.* Interested parties should check the above Web page regularly for information regarding the webinar and Challenge, as it becomes available.

Issues on Which DOE Seeks Comment

DOE is seeking comments and views of interested parties on the following issues:

○ The performance requirements laid out in the specification.

○ The price targets laid out in the specification.

○ The applicability of the performance requirements to various types of commercial buildings.

○ The feasibility of developing a technology that meets the performance and price targets laid out in the specification.

Submission of Comments

DOE will accept comments, data, and information regarding the draft *Specification* no later than the date specified under the **DATES** heading.

Comments, data, and information submitted via DOE's email address should be provided in WordPerfect, Microsoft Word, PDF, or text (ASCII) file format. Interested parties should avoid the use of special characters or any form of encryption, and wherever possible, comments should include the electronic signature of the author. Comments, data, and information submitted to DOE via regular mail may include one signed paper original.

According to 10 CFR 1004.11, any person submitting information that he or she believes to be confidential and exempt by law from public disclosure should submit two copies: one copy of the document including all the information believed to be confidential, and one copy of the document that does not include the information believed to be confidential. DOE will make its own determination as to the confidential status of the information and treat it according to its determination.

Factors of interest to DOE when evaluating requests to treat submitted information as confidential include:

(1) A description of the items;

(2) Whether and why such items are customarily treated as confidential within the industry;

(3) Whether the information is generally known by or available from other sources;

(4) Whether the information has previously been made available to others without obligation concerning its confidentiality;

(5) An explanation of the competitive injury to the submitting person which would result from public disclosure;

(6) A date upon which such information might lose its confidential nature due to the passage of time; and

(7) Why disclosure of the information would be contrary to the public interest.

Issued in Washington, DC, on March 29, 2013.

Kathleen B. Hogan,

Deputy Assistant Secretary, Energy Efficiency and Renewable Energy.

[FR Doc. 2013–07972 Filed 4–4–13; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9530–3]

Agency Information Collection Activities OMB Responses

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This document announces the Office of Management and Budget (OMB) responses to Agency Clearance requests, in compliance with the Paperwork Reduction Act (44 U.S.C. 3501 et. seq.). 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 regulations are listed in 40 CFR part 9 and 48 CFR chapter 15.

FOR FURTHER INFORMATION CONTACT: Rick Westlund (202) 566–1682, or email at *westlund.rick@epa.gov* and please refer to the appropriate EPA Information Collection Request (ICR) Number.

SUPPLEMENTARY INFORMATION:

OMB Responses To Agency Clearance Requests

OMB Approvals

EPA ICR Number 0155.11; Certification of Pesticide Applicators (Renewal); 40 CFR parts 152 and 171; was approved on 03/01/2013; OMB Number 2070–0029; expires on 02/28/2015; Approved without change.

EPA ICR Number 1899.07; NSPS for Hospital/Medical/Infectious Waste Incinerators; 40 CFR part 60 subparts A and Ce; and 40 CFR part 62 subparts A and HHH; was approved on 03/01/2013; OMB Number 2060–0422; expires on 03/31/2016; Approved without change.

EPA ICR Number 2436.02; Hazardous Chemical Reporting: Revisions to the Emergency and Hazardous Chemical Inventory Forms (Tier I and Tier II) (Final Rule); 40 CFR part 370; was approved on 03/01/2013; OMB Number 2050–0206; expires on 03/31/2016; Approved without change.

EPA ICR Number 1062.13; NSPS for Coal Preparation and Processing Plants; 40 CFR part 60 subparts A and Y; was approved on 03/08/2013; OMB Number

2060–0122; expires on 03/31/2016; Approved without change.

EPA ICR Number 2348.03; NESHAP for Paints and Allied Products Manufacturing Area Source Category; 40 CFR part 63 subparts A and CCCCCCC; was approved on 03/08/2013; OMB Number 2060–0633; expires on 03/31/2016; Approved without change.

EPA ICR Number 2352.03; NESHAP for Asphalt Processing and Asphalt Roofing Manufacturing; 40 CFR part 63 subparts A and AAAAAAA; was approved on 03/08/2013; OMB Number 2060–0634; expires on 03/31/2016; Approved without change.

EPA ICR Number 1052.10; NSPS for Fossil-Fuel-Fired Steam Generating Units; 40 CFR part 60 subparts A and D; was approved on 03/08/2013; OMB Number 2060–0026; expires on 03/31/2016; Approved without change.

EPA ICR Number 1066.07; NSPS for Ammonium Sulfate Manufacturing Plants; 40 CFR part 60 subparts A and PP; was approved on 03/10/2013; OMB Number 2060–0032; expires on 03/31/2016; Approved without change.

EPA ICR Number 1969.05; NESHAP for Miscellaneous Organic Chemical Manufacturing; 40 CFR part 63 subparts A and FFFF; was approved on 03/11/2013; OMB Number 2060–0533; expires on 03/31/2016; Approved without change.

EPA ICR Number 1730.09; NSPS for Hospital/Medical/Infectious Waste Incinerators; 40 CFR part 60 subparts A and Ec; was approved on 03/11/2013; OMB Number 2060–0363; expires on 03/31/2016; Approved without change.

EPA ICR Number 1772.06; EPA's ENERGY STAR Program in the Commercial and Industrial Sectors (Renewal); was approved on 03/11/2013; OMB Number 2060–0347; expires on 03/31/2016; Approved without change.

EPA ICR Number 1847.06; Emission Guidelines for Large Municipal Waste Combustors Constructed on or Before September 20, 1994; 40 CFR part 60 subparts A and Cb; was approved on 03/18/2013; OMB Number 2060–0390; expires on 03/31/2016; Approved without change.

EPA ICR Number 2317.02; Generator Standards Applicable to Laboratories Owned by Eligible Academic Entities (Renewal); 40 CFR part 262 subpart K; was approved on 03/18/2013; OMB Number 2050–0204; expires on 03/31/2016; Approved with change.

EPA ICR Number 2382.03; Identification of Non-Hazardous Secondary Materials That Are Solid Waste (Final Rule) (Revision); 40 CFR 260.22 and 260.31(c); was approved on 03/18/2013; OMB Number 2050–0205; expires on 03/31/2016; Approved without change.

EPA ICR Number 1801.11; NESHAP for the Portland Cement Manufacturing Industry; 40 CFR part 63, subparts A and LLL; was approved on 03/18/2013; OMB Number 2060–0416; expires on 03/31/2016; Approved without change.

EPA ICR Number 1692.07; NESHAP for Petroleum Refineries; 40 CFR part 63 subparts A and CC; was approved on 03/19/2013; OMB Number 2060–0340; expires on 03/31/2016; Approved with change.

EPA ICR Number 2207.05; Exchange Network Grants Progress Reports (Change form); was approved on 03/19/2013; OMB Number 2025–0006; expires on 04/30/2015; Approved with change.

EPA ICR Number 1849.06; Landfill Methane Outreach Program (Renewal); was approved on 03/19/2013; OMB Number 2060–0446; expires on 03/31/2016; Approved without change.

EPA ICR Number 1813.08; Regional Haze Regulations (Renewal); 40 CFR part 51; was approved on 03/19/2013; OMB Number 2060–0421; expires on 03/31/2016; Approved without change.

EPA ICR Number 0160.10; Pesticide Registration Application, Notification and Report for Pesticide Producing Establishments (Renewal); 40 CFR part 167; was approved on 03/19/2013; OMB Number 2070–0078; expires on 03/31/2016; Approved without change.

EPA ICR Number 0801.19; Requirements for Generators, Transporters, and Waste Management Facilities under the RCRA Hazardous Waste Manifest System (Renewal); 40 CFR parts 262–265; was approved on 03/20/2013; OMB Number 2050–0039; expires on 05/31/2015; Approved with change.

EPA ICR Number 0820.12; Hazardous Waste Generator Standards (Renewal); 40 CFR 262.34, 262.40(c), 262.43, 262.44(c), 262.53–262.57, 262.60, 265.190–265.193 and 265.196; was approved on 03/20/2013; OMB Number 2050–0035; expires on 10/31/2014; Approved without change.

EPA ICR Number 0586.12; TSCA Section 8(a) Preliminary Assessment Information Rule (PAIR); 40 CFR parts 712, 766, and 792; was approved on 03/28/2013; OMB Number 2070–0054; expires on 03/31/2016; Approved with change.

Short Term Extension of Expiration Date

EPA ICR Number 2334.03; NESHAP for Petroleum Refineries (Final Rule); a short term extension of the expiration date was granted by OMB on 03/01/2013; OMB Number 2060–0619; expires on 03/31/2013.

Comment Filed

EPA ICR Number 2463.01; Recordkeeping and Reporting for Diesel Fuel Produced by Transmix Producers (Direct Final); in 40 CFR 80.511(b)(4), 80.513, 80.572(d) and 597(d)(3)(ii); OMB filed comment on 03/01/2013.

John Moses,

Director, Collections Strategies Division.

[FR Doc. 2013–07889 Filed 4–4–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2012–0688; FRL–9530–2]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Comment Request; NESHAP for Plastic Parts and Products Surface Coating (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that an Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval. This is a request to renew an existing approved collection. The ICR which is abstracted below describes the nature of the collection and the estimated burden and cost.

DATES: Additional comments may be submitted on or before May 6, 2013.

ADDRESSES: Submit your comments, referencing docket ID number EPA–HQ–OECA–2012–0688, to: (1) EPA online, using www.regulations.gov (our preferred method), or by email to: *docket.oeca@epa.gov*, or by mail to: EPA Docket Center (EPA/DC), Environmental Protection Agency, Enforcement and Compliance Docket and Information Center, mail code 28221T, 1200 Pennsylvania Avenue NW., Washington, DC 20460; and (2) OMB at: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Learia Williams, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460; telephone number: (202) 564–4113; fax number:

(202) 564–0050; email address: *williams.learia@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. On October 17, 2012 (77 FR 63813), EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). EPA received no comments. Any additional comments on this ICR should be submitted to both EPA and OMB within 30 days of this notice.

EPA has established a public docket for this ICR under docket ID number EPA–HQ–OECA–2012–0688, which is available for either public viewing online at *http://www.regulations.gov*, or in person viewing at the Enforcement and Compliance Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Avenue NW, Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566–1744, and the telephone number for the Enforcement and Compliance Docket is (202) 566–1752.

Use EPA's electronic docket and comment system at *http://www.regulations.gov* to either 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, Confidentiality of Business Information (CBI), or other information whose public disclosure is restricted by statute. For further information about the electronic docket, go to *www.regulations.gov.*

Title: NESHAP for Plastic Parts and Products Surface Coating (Renewal).

ICR Numbers: EPA ICR Number 2044.05, OMB Control Number 2060–0537.

ICR Status: This ICR is scheduled to expire on June 30, 2013. Under OMB regulations, the Agency may continue either to conduct or sponsor the collection of information while this submission is pending at OMB.

Abstract: The affected entities are subject to the General Provisions of the NESHAP at 40 CFR part 63, subpart A, and any changes, or additions to the Provisions specified at 40 CFR part 63, subpart PPPP. Owners or operators of the affected facilities must submit an initial notification report, performance tests, and periodic reports and results. Owners or operators are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. Reports are required semiannually at a minimum.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 91 hours per response. ''Burden'' means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously-applicable instructions and requirements which have subsequently changed; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Respondents/Affected Entities: Plastic parts and products surface coating facilities.

Estimated Number of Respondents: 832.

Frequency of Response: Initially, occasionally, and semiannually.

Estimated Total Annual Hour Burden: 322,467.

Estimated Total Annual Cost: $31,489,594, which includes $31,223,994 in labor costs, $16,000 in capital/startup costs, and $249,600 in operation and maintenance (O&M) costs.

Changes in the Estimates: There is an increase in the total estimated burden as currently identified in the OMB Inventory of Approved Burdens. The adjustment increase in burden from the most-recently approved ICR is due to an increase in the number of sources subject to the NESHAP, as well as to an adjustment increase in labor rates. This ICR uses the most recent labor rates in calculating all burden costs. The growth in the respondent universe also results in a corresponding increase in the total O&M costs.

John Moses,

Director, Collection Strategies Division.

[FR Doc. 2013–07887 Filed 4–4–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPA–2007–0584; FRL–9530–1]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Spill Prevention, Control and Countermeasure (SPCC) Plans (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency has submitted an information collection request (ICR), ''Spill Prevention, Control and Countermeasures (SPCC) Plans (Renewal)'' (EPA ICR No. 0328.16, OMB Control No. 2050–0021) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). This is a proposed extension of the ICR, which is currently approved through June 30, 2013. Public comments were previously requested via the **Federal Register** (77 FR 74659) on December 17, 2012 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before May 6, 2013.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ-OPA–2007–0584, to (1) EPA online using *www.regulations.gov* (our preferred method), by email to *RCRA-Docket@epa.gov*, or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave., NW., Washington, DC 20460, and (2) OMB via email to *oira_submission@omb.eop.gov*. Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless

the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: George W. Denning, Office of Emergency Management, Mail Code 5104A, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 564–2404; fax number: (202) 564–2625; email address: *Denning.George@epa.gov*.

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets*.

Abstract: The authority for EPA's oil pollution prevention requirements is derived from section 311(j)(1)(C) of the Clean Water Act, as amended by the Oil Pollution Act of 1990. EPA's regulation is codified at 40 CFR part 112. An SPCC Plan will help an owner or operator identify the necessary procedures, equipment and resources to respond to prevent an oil spill and to respond to an oil spill in a timely manner. If implemented effectively, the SPCC Plan is expected to prevent oil spills and reduce the impact and severity of oil spills. Although the owner or operator is the primary data user, EPA may also require the owner or operator to submit data to the Agency in certain situations to ensure facilities comply with the SPCC regulation and to help allocate response resources. State and local governments may use the data, which are not generally available elsewhere and can assist local emergency preparedness planning efforts. EPA does not require an owner or operator to submit SPCC Plans, but may request the SPCC Plan during a facility inspection or an oil spill incident for review. The SPCC regulation requires the owner or operator maintain a complete copy of the Plan at the facility if the facility is normally attended at least fours hours per day or at the nearest field office if the facility is not so attended. The rule also requires that the Plan be available to the Regional Administrator for on-site review during normal working hours (40 CFR 112.3(e)).

Form Numbers: None.

Respondents/affected entities: Private facilities, State/Local/Tribal governments.

Respondent's obligation to respond: Mandatory per 40 CFR part 112.

Estimated number of respondents: 670,048 (total).

Frequency of response: Less than once per year.

Total estimated burden: 8,798,928 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $987,220,025, includes $186,674,814 annualized capital or operation and maintenance costs.

Changes in the Estimates: Differences in burden and costs from the previous ICR are attributed to adjustments for wage rates, unit costs, and the projected universe of facilities.

John Moses,

Director, Collection Strategies Division.

[FR Doc. 2013–07888 Filed 4–4–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9008–5]

Environmental Impacts Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–7146 or *http://www.epa.gov/compliance/nepa/.*

Weekly receipt of Environmental Impact Statements Filed 03/25/2013 Through 03/29/2013

Pursuant to 40 CFR 1506.9.

Notice

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *http://www.epa.gov/compliance/nepa/eisdata.html.*

EIS No. 20130080, Final EIS, BLM, CA, Clear Creek Management Area Proposed Resource Management Plan, Review Period Ends: 05/06/2013, Contact: Sky Murphy (831) 630–5039.

EIS No. 20130081, Draft EIS, USFWS, IN, Fowler Ridge Wind Habitat Conservation Plan and Incidental Take Permit, Comment Period Ends: 06/04/2013, Contact: Scott Pruitt 812–334–4261.

EIS No. 20130082, Draft Supplement, FERC, ME, Downeast Liquefied Natural Gas (LNG) Project, Comment Period Ends: 05/20/2013, Contact: Shannon Crosley 202–502–8853.

EIS No. 20130083, Draft EIS, NPS, NC, Fort Raleigh National Historic Site Draft General Management Plan, Comment Period Ends: 06/04/2013, Contact: David Libman 404–507–5701.

EIS No. 20130084, Final EIS, USFS, CO, Black Mesa Vegetation Management Project, Rio Grande National Forest, Review Period Ends: 05/17/2013, Contact: Diana McGinn 719–852–6241.

EIS No. 20130085, Final EIS, USACE, OK, Eufaula Lake Shoreline Management Plan Revision and Master Plan Supplement, Review Period Ends: 05/06/2013, Contact: Jeff Knack 918–669–7666.

Dated: April 2, 2013.

Cliff Rader,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2013–07982 Filed 4–4–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2009–0927; FRL–9799–4]

Mandatory Reporting of Greenhouse Gases: Notice of Data Availability Regarding Global Warming Potential Values for Certain Fluorinated Greenhouse Gases and Fluorinated Heat Transfer Fluids

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of data availability and request for comment.

SUMMARY: The EPA is announcing to the public the availability of estimated global warming potentials, as well as data and analysis submitted in support of them, for eight fluorinated heat transfer fluids. We are requesting comments on the estimated global warming potentials and the data and analysis supporting them. We are also requesting comment on the cited global warming potentials for 35 other fluorinated greenhouse gases and fluorinated heat transfer fluids for which we do not currently possess supporting data and analysis. The EPA is requesting comment on the global warming potentials of all 43 chemicals as we consider adding these global warming potentials to the Greenhouse Gas Reporting rule.

DATES: Comments must be received on or before May 6, 2013.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2009–0927, by one of the following methods:

• *Federal eRulemaking Portal: http://www.regulations.gov*: Follow the online instructions for submitting comments.
• *Email: GHGReportingFGHG@epa.gov.*
• Fax: (202) 566–1741.
• *Mail:* EPA Docket Center, Attention Docket EPA–HQ–OAR–2009–0927, Mail code: 2822T, 1200 Pennsylvania Avenue NW., Washington, DC 20460.
• *Hand Delivery:* EPA Docket Center, Public Reading Room, Room 3334, EPA West Building, Attention Docket EPA–HQ–OAR–2009–0927, 1301 Constitution Avenue NW., Washington, DC 20004. 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–2009–0927. 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.* 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 email comment directly to EPA without going through *http://www.regulations.gov* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, 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 *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at EPA's Docket Center, Public Reading Room, EPA West Building, Room 3334, 1301 Constitution Avenue NW., Washington, DC 20004. This Docket Facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Air Docket is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: Deborah Ottinger, Climate Change Division, Office of Atmospheric Programs (6207J), Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460; telephone number: (202) 343–9149; fax number: (202) 343–2342; email address: *ottinger.deborah@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. What is today's notice about?

• The EPA is making available for public comment estimated GWPs for the eight fluorinated heat transfer fluids (HTFs) listed in Table 1 of this notice as well as data and analysis submitted in support of those GWPs.
• The EPA is also making available for public comment cited GWPs for the 35 fluorinated GHGs and fluorinated HTFs listed in Table 2 of this notice. The EPA does not currently possess supporting data and analysis for these GWPs.
• Both sets of chemicals and their GWPs are being considered for addition to Table A–1 to subpart A of part 98, the compendium of GWPs used to convert tons of chemical into tons of carbon dioxide equivalent (CO_2e) under the Greenhouse Gas Reporting Program.

B. How does this notice relate to the forthcoming proposed rule titled ''2013 Revisions to the Greenhouse Gas Reporting Rule and Proposed Confidentiality Determinations for New or Substantially Revised Data Elements''?

In the proposed rule signed March 8, 2013, titled ''2013 Revisions to the Greenhouse Gas Reporting Rule and Proposed Confidentiality Determinations for New or Substantially Revised Data Elements'' (hereinafter referred to as the ''2013 Technical Corrections Proposed Rule''), the EPA is proposing to amend subpart A, General Provisions, to propose GWPs for certain fluorinated greenhouse gases not currently listed in Table A–1 to subpart A. This notice requests comment on GWPs for fluorinated GHGs and fluorinated HTFs for which documented GWPs were not available in time for inclusion in the 2013 Technical Corrections Proposed Rule. The comments submitted in response to this notice are intended to inform a potential future rulemaking to amend Table A–1 to subpart A to add the GWPs of some or all of the fluorinated GHGs and fluorinated HTFs listed in this notice.

C. Where can I get the information?

All of the information can be obtained through the Docket and at *http://www.regulations.gov* (see **ADDRESSES** section above for docket contact information).

D. What is the EPA taking comment on and what supporting documentation do I need to include in my comments?

The EPA requests comment on topics including but not limited to the following:
• For the fluorinated HTFs in Table 1 of this notice, the reliability, including the likely accuracy and precision, of the GWPs listed in Table 1 given the data and analysis submitted in support of them, and
• The completeness, quality, and transparency of the data and analysis submitted in support of the GWPs in Table 1 of this notice.
• For the fluorinated GHGs and HTFs in Table 2 of this notice, the reliability, including the likely accuracy and precision, of the GWPs listed, and
• The accuracy of the chemical names and formulas listed.

For the fluorinated HTFs in Table 1 of this notice, the EPA is specifically seeking comment on the extent to which the supporting data and analysis includes the following:
• Data and analysis related to the low-pressure gas phase infrared absorption spectrum of the fluorinated GHG.
• Data and analysis related to the estimated atmospheric lifetime of the fluorinated GHG (reaction mechanisms and rates, including e.g., photolysis and reaction with atmospheric components such as OH, O_3, CO, and water), including descriptions of the measurements or modeling.
• The radiative transfer analysis that integrates the lifetime and infrared absorption spectrum data to calculate the GWP.
• Any published or unpublished studies of the GWP of the gas.

Where quantitative structure–activity relationship (QSAR) models have been used, the EPA is seeking comment on the extent to which the data and

analysis include information documenting the level of accuracy of the QSAR-derived GWP, including:

- Information on how the structure of the ''target'' fluorinated GHG is similar to the structures of the fluorinated GHGs used to model the radiative forcing and/or reaction rate of the ''target'' fluorinated GHG.
- Information on the quality (i.e., accuracy and precision) and quantity of the measurements of the radiative forcings and/or reaction rates of the fluorinated GHGs used to model these parameters for the ''target'' fluorinated GHG.
- Estimated uncertainties of the modeled forcings and/or reaction rates.
- Descriptions and results of any efforts to validate the QSAR model(s).

E. What should I consider as I prepare my comments for EPA?

- Explain your views as clearly as possible.
- Describe any assumptions that you used.
- Provide any technical information or data you used that support your views.
- Provide specific examples to illustrate your concerns.
- Offer alternatives.
- Make sure to submit your comments by the comment period deadline identified.
- To ensure proper receipt by EPA, identify the appropriate docket identification number in the subject line on the first page of your response. It would also be helpful if you provided the name, date, and **Federal Register** citation related to your comments.

F. Submitting Confidential Business Information (CBI)

Do not submit information you are claiming as CBI to EPA through *http://www.regulations.gov* or email. Clearly mark the part of the information that you claim to be CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. 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.

II. Background

Table A–1 to subpart A of 40 CFR part 98 (''Table A–1'') is a compendium of GWP values of certain GHGs that are required to be reported under one or more subparts of the Greenhouse Gas Reporting rule (''Part 98''). These GWPs are used to convert tons of chemical into tons of CO_2-equivalent for purposes of various calculations and reporting under the rule. As acknowledged in the **Federal Register** notice for the final Part 98 (74 FR 56348, October 30, 2009), it is the EPA's intent to periodically update Table A–1 as GWPs are evaluated or re-evaluated by the scientific community. This will provide a more accurate and complete account of the atmospheric impacts of GHG emissions and supplies.

Table A–1 of Part 98 currently includes 10 fluorinated HTFs of which EPA is aware, but there are a number that it does not include. Of the 42 fluorinated HTFs listed in this notice (none of which is on Table A–1 of Part 98), electronics facilities reported emissions of 17 under the Greenhouse Gas Reporting Program (GHGRP). Electronics facilities reported use of another four in a 2009 industry survey by the International SEMATECH Manufacturing Initiative (Technology Transfer #09065014A–TR). Other HTFs (those with vapor pressures below 1 mm Hg at 25 degrees C) may be reported for the first time this year because of an expanded definition of fluorinated HTF that went into effect in 2012. Several of the fluorinated HTFs in this notice are fully fluorinated. Fully fluorinated compounds are likely to have long atmospheric lifetimes and high GWPs.[1]

There are two primary suppliers of fluorinated HTFs used in the United States: 3M Company (3M) and Solvay. After evaluating the reports submitted under subpart I, the EPA contacted 3M and Solvay and requested any data and information they had regarding the GWPs of the fluorinated HTFs that they supplied.

3M responded with estimated GWPs and supporting data and analysis for eight fluorinated HTFs collectively composed of nine fluorinated compounds. (One of the HTFs, FC–77, is a blend of two fluorinated compounds.) For one of the fluorinated compounds, C_8F_{18}, the EPA is proposing a GWP in the 2013 Technical Corrections Proposed Rule. Thus, the EPA is not requesting comment on the GWP of C_8F_{18} through this action. However, the EPA is requesting comment on the GWPs and supporting data and analysis for the other eight compounds, which are listed in Table 1 of this notice. These compounds (along with the 3M HTFs already included on Table A–1 of Part 98) account for most of the emissions of 3M-supplied HTFs reported to EPA under subpart I to date (i.e., in 2012).

Solvay indicated that it generally did not possess data and analysis to support estimated GWPs for the Solvay-supplied HTFs that are not already on Table A–1 of Part 98.[2] Table 2 of this notice therefore includes all of the Solvay-supplied fluorinated HTFs of which EPA is aware and which are not already included on Table A–1. It also includes some 3M-supplied fluorinated HTFs (and one fluorinated GHG used as a chamber cleaning gas) for whose estimated GWPs 3M did not submit supporting data and analysis. 3M indicates that some of these HTFs are no longer produced.

For several of the fluorinated HTFs (and for the fluorinated GHG) in Table 2 of this notice, approximate GWPs have been presented or published (e.g., in presentations to the EPA or in material safety data sheets (MSDSs)) without accompanying explanation or documentation of how those GWPs have been developed. For a large subset of these fully fluorinated chemicals, GWPs of 10,000 were identified in a presentation given by 3M to EPA. For some of these chemicals, different GWPs were identified in other sources, such as MSDSs issued by 3M or Solvay. These are the GWPs that are included in Table 2. The EPA does not intend to add the cited GWPs for these compounds to Table A–1 of Part 98 without supporting data and analysis. We are therefore continuing to assemble and evaluate information regarding the GWPs for the compounds in Table 2 of this notice. We request comment on these GWPs and on the accuracy of the listed chemical names and formulas for the compounds.

III. GWP Values on Which EPA is Seeking Comment

[1] Fully fluorinated compounds are defined as compounds that contain only single bonds and in which all available valence locations are filled by fluorine atoms (e.g., saturated perfluorocarbons; fully fluorinated linear, branched and cyclic alkanes; fully fluorinated ethers; fully fluorinated tertiary amines; fully fluorinated aminoethers; and perfluoropolyethers).

[2] Solvay provided a peer-reviewed paper regarding a fluorinated compound, PFPMIE, that is already on Table A–1 and that is sold under the trade name of Galden HT 70. (There are multiple PFPMIEs, which have the general chemical structure $F_3C(OCFCF_3CF_2)_m(OCF_2)_nOCF_3$. The PFPMIE that is listed on Table A–1 and is the primary component of HT 70 is the simplest version, with m=n=1.) In addition, Solvay submitted an infrared absorption spectrum for another fluorinated HTF that it imports into the U.S., Galden HT–110.

TABLE 1—F–HTFS WITH DOCUMENTED GWPS

Trade name(s)	CAS No.	Chemical name and formula	Submitted GWP	Source of submitted GWP
Fluorinert FC–77 (component); Fluorinert FC–75.	335–36–4	Perfluoro-2-butyltetrahydro-furan. $C_8F_{16}O$	9,600	GWP and calculation methodology provided by manufacturer
Fluorinert FC–3283	338–83–0	Perfluoro-tripropylamine (PTPA) $(C_3F_7)_3N$	8,690	GWP and calculation methodology provided by manufacturer
Fluorinert FC–40	1064698–37–8	Perfluoro-tributylamine (PTBA) $(C_4F_9)_3N$	9,020	GWP and calculation methodology provided by manufacturer
Fluorinert FC–3284, PF–5052	382–28–5	Perfluoromethyl morpholine (PMM). $C_5F_{11}NO$	9,500	GWP and calculation methodology provided by manufacturer
Fluorinert FC–770	1093615–61–2	Perfluoro-isopropyl morpholine (PIPM). $C_7F_{15}NO$	11,000	GWP and calculation methodology provided by manufacturer
Novec 7300, HFE–7300	132182–92–4	1,1,1,2,2,3,4,5,5,5-decafluoro-3-methoxy-4-trifluoromethyl-pentane. $CF_3CF_2CF(OCH_3)CF(CF_3)_2$	310	GWP and calculation methodology provided by manufacturer
Novec 7500, HFE–7500	297730–93–9	3-ethoxy-1,1,1,2,3,4,4,5,5,6,6,6-dodecafluoro-2-trifluoromethyl-hexane. $CF_3CF_2CF_2CF(OC_2H_5)CF(CF_3)_2$	100	GWP and calculation methodology provided by manufacturer
F–HTFs with Vapor Pressure Less than 1 mm Hg				
Fluorinert FC–70	338–84–1	Perfluoro-triamylamine (PTAA) $(C_5F_{11})_3N$	8,900	GWP and calculation methodology provided by manufacturer

TABLE 2—F–GHGS AND F–HTFS FOR WHOSE GWPS DOCUMENTATION IS NOT AVAILABLE

Trade name(s)	CAS No.	Chemical name and formula	Cited GWP	Source of cited GWP
Heptafluorobutanoyl fluoride	773–14–8	C_4F_8O	8,700	Identified in Pruette et al. (2000) [a]
Fluorinert FC–3255, FC–104	335–36–4	Predominantly C_5-C_{18}	10,000	Identified in presentation to EPA [b]
Fluorinert FC–5311, Phenanthrene.	306–91–2	Perfluoroperhydrophenanthrene $C_{14}F_{24}$	10,000	Identified in presentation to EPA [b]
Fluorinert FC–5320	86508–42–1	Perfluoro-compounds C_5-C_{18}	>5,000	Identified in manufacturer's literature [c]
Fluorinert FC–8270	338–83–0	Perfluoro compounds (primarily compounds with 9 carbons).	10,000	Identified in presentation to EPA [b]
Novec 7600, HFE–7600	870778–34–0	1,1,1,2,3,3-Hexafluoro-4-(1,1,2,3,3,3-hexafluoroprop-oxy)-pentane. $C_8H_6F_{12}O$	700	Identified in manufacturer's literature [d]
H-Galden ZT–130	188690–77–9	$HCF_2OCF_2OCF_2CF_2OCF_2H$	3000–5000	Identified in presentation to EPA [b]
H-Galden ZT–150	188690–77–9	$HCF_2OCF_2OCF_2CF_2OCF_2H$	3000–5000	Identified in presentation to EPA [b]
H-Galden ZT–180	188690–77–9	$HCF_2OCF_2OCF_2CF_2OCF_2H$	3000–5000	Identified in presentation to EPA [b]
H-Galden ZV60	Not Available	HCF_2O-$(CF_2O)_p$-$(CF_2CF_2O)_q$-CF_2H. (ratio of p/q is 2/3)	3,000–5,000	Identified in presentation to EPA [b]
H-Galden ZV85, ZT–85	Not Available	Not Available	3,000–5,000	Identified in presentation to EPA [b]
H-Galden ZV100	Not Available	Not Available	3,000–5,000	Identified in presentation to EPA [b]
H-Galden ZV135	Not Available	Not Available	3,000–5,000	Identified in presentation to EPA [b]
Galden DET	Not Available	$CF_3(OCFCF_3CF_2)_n$-$(OCF_2)_m$-OCF_3.	10,000	Identified in presentation to EPA [b]
Galden E85	Not Available	$CF_3(OCFCF_3CF_2)_n$-$(OCF_2)_m$-OCF_3.	10,000	Identified in presentation to EPA [b]
Galden HT–55	69991–67–9	$CF_3(OCFCF_3CF_2)_n$-$(OCF_2)_m$-OCF_3. n = 2.03 to 9.26 [h] m = 0.04 to 0.19	10,000	Identified in presentation to EPA [b]

TABLE 2—F–GHGS AND F–HTFS FOR WHOSE GWPS DOCUMENTATION IS NOT AVAILABLE—Continued

Trade name(s)	CAS No.	Chemical name and formula	Cited GWP	Source of cited GWP
Galden HT–90	69991–67–9	$CF_3(OCFCF_3CF_2)_n$-$(OCF_2)_m$-OCF_3. n = 2.03 to 9.26 [h]) m = 0.04 to 0.19	10,000	Identified in presentation to EPA [b]
Galden HT–110	69991–67–9	$CF_3(OCFCF_3CF_2)_n$-$(OCF_2)_m$-OCF_3. n = 2.03 to 9.26 [h] m = 0.04 to 0.19	10,000	Identified in presentation to EPA [b,e]
Galden HT–135	69991–67–9	$CF_3(OCFCF_3CF_2)_n$-$(OCF_2)_m$-OCF_3. n = 2.03 to 9.26 [h] m = 0.04 to 0.19	10,000	Identified in presentation to EPA [b]
Galden HT–170	69991–67–9	$CF_3(OCFCF_3CF_2)_n$-$(OCF_2)_m$-OCF_3. n = 2.03 to 9.26 [h] m = 0.04 to 0.19	10,000	Identified in presentation to EPA [b]
Galden D02—TS	69991–67–9	$CF_3(OCFCF_3CF_2)_n$-$(OCF_2)_m$-OCF_3.	10,000	Identified in presentation to EPA [b]
Galden D02—TSX	69991–67–9	$CF_3(OCFCF_3CF_2)_n$-$(OCF_2)_m$-OCF_3.	None provided	No GWP found
Galden PFS 2	69991–67–9 and 9002–84–0.	$CF_3(OCFCF_3CF_2)_n$-$(OCF_2)_m$-OCF_3.	None provided	HTF identified in distributor's literature [f]
F–HTFs with Vapor Pressure Less than 1 mm Hg				
Fluorinert FC–43	311–89–7	$N(CF_2CF_2CF_2CF_3)_3$	10,000	Identified in presentation to EPA [b]
Fluorinert FC–5312	338–84–1	Perfluoro compounds (primarily with 15 carbons).	10,000	Identified in presentation to EPA [b]
Galden D02	69991–67–9	$CF_3(OCFCF_3CF_2)_n$-$(OCF_2)_m$-OCF_3.	10,000	Identified in presentation to EPA [b]
Galden D03	69991–67–9	$CF_3(OCFCF_3CF_2)_n$-$(OCF_2)_m$-OCF_3.	10,000	Identified in presentation to EPA [b]
Galden D05	69991–67–9	$CF_3(OCFCF_3CF_2)_n$-$(OCF_2)_m$-OCF_3.	10,000	Identified in presentation to EPA [b]
Galden HS–240	69991–67–9	$CF_3(OCFCF_3CF_2)_n$-$(OCF_2)_m$-OCF_3. n = 6.4 to 7.3 [h] m = 0.1 to 0.15	10,000	Identified in presentation to EPA [b]
Galden HS–260	69991–67–9	$CF_3(OCFCF_3CF_2)_n$-$(OCF_2)_m$-OCF_3. n = 6.4 to 7.3 [h] m = 0.1 to 0.15	10,000	Identified in presentation to EPA [b]
Galden HT–200	69991–67–9	$CF_3(OCFCF_3CF_2)_n$-$(OCF_2)_m$-OCF_3. n = 2.03 to 9.26 [h] m = 0.04 to 0.19	10,000	Identified in presentation to EPA [b]
Galden HT–230	69991–67–9	$CF_3(OCFCF_3CF_2)_n$-$(OCF_2)_m$-OCF_3. n = 2.03 to 9.26 [h] m = 0.04 to 0.19	None provided	HTF identified in distributor's literature [g]
Galden LS–200	69991–67–9	$CF_3(OCFCF_3CF_2)_n$-$(OCF_2)_m$-OCF_3. n = 5.2 to 6.1 [h] m = 0.1 to 0.12	10,000	Identified in presentation to EPA [b]
Galden LS–215	69991–67–9	$CF_3(OCFCF_3CF_2)_n$-$(OCF_2)_m$-OCF_3. n = 5.2 to 6.1 [h] m = 0.1 to 0.12	10,000	Identified in presentation to EPA [b]
Galden LS–230	69991–67–9	$CF_3(OCFCF_3CF_2)_n$-$(OCF_2)_m$-OCF_3. n = 5.2 to 6.1 [h] m = 0.1 to 0.12	10,000	Identified in presentation to EPA [b]

[a] Pruette, L., S. Karecki, R. Reif, L. Tousignant, W. Reagan, S. Kesari, and L. Zazzera. "Evaulation of C4F8O as an Alternative Plasma-Enhanced Chemical Vapor Deposition Chamber Clean Chemistry." Journal of the Electrochemical Society, 147 (3): 1149–1153, 2000.

[b] 3M Company. "Greenhouse Gas Reporting of Heat Transfer Fluids." Presentation by Kurt Werner of 3M Electronics Markets Materials Division. Presented to the EPA, January 2011. Available in Docket No. EPA–HQ–OAR–2011–0512.

[c] 3M Company. "Material Safety Data Sheet: 3M™ Fluorinert™ FC–5320 Electronic Liquid." 2012. Available online at: *http://multimedia.3m.com/mws/mediawebserver?SSSSSuUn_zu8l00x4xtZm8m94v70k17zHvu9lxtD7SSSSSS—*

[d] 3M Company. "Material Safety Data Sheet: 3M™ Novec™ 7600 Engineered Fluid." 2011. Available online at: *http://multimedia.3m.com/mws/mediawebserver?mwsId=SSSSSuUn_zu8l00xMxmGmxtx4v70k17zHvu9lxtD7SSSSSS—*.

[e] Solvay provided an infrared (IR) spectrum for this compound, but not an estimated atmospheric lifetime or GWP.

[f] *http://www.sigmaaldrich.com/catalog/product/aldrich/374431?lang=en&region=US.*
[g] *https://www.lesker.com/newweb/fluids/msds/Galden_HT230.pdf.*
[h] In the chemical formulas for the Galden series, ''n'' and ''m'' indicate the number of times each group (in parentheses) is repeated in the compound. While ''n'' and ''m'' are integers in any single molecule, the Galden HTFs are typically made up of mixtures of different molecules. The values for ''n'' and ''m'' for any single Galden HTF represent averages for that HTF. Table 2 provides the ranges of the average values of ''n'' and ''m'' for the Solvay HTFs in each Galden series (Galden HT, LS, etc.).

IV. Summary of EPA Assessment of Submitted GWPs and the Data and Analysis Supporting Them

The EPA completed a review of the GWPs listed in Table 1 of this notice and the data and analysis submitted in support of them. That assessment is available in the docket, together with the submitted data and analyses. In general, we found that the data and methods used to estimate the GWPs were reasonable and that the GWPs were consistent with what would be expected for compounds of the types analyzed. However, there were some limitations to the data and analysis. First, in some cases the transparency of the data and analysis were limited because some of the reports containing the detailed background information were not available for review in time for this notice. Second, some of the data were of uncertain quality because they were based on an unpublished master's thesis. Third, because some of the analyses were performed in the early 1990s, some of the models used to estimate lifetimes or radiative efficiencies were out of date. Fourth, in one case (PTAA), radiative efficiency estimates were based on a quantitative structural activity relationship (QSAR) of uncertain predictive ability. Fifth, the atmospheric lifetime for one of the short-lived compounds (HFE–7300) was estimated based on an atmospheric lifetime for methane that is lower than the currently accepted lifetime, resulting in an underestimated lifetimes for that compound. Finally, for the six long-lived compounds, experimental limitations prevented 3M or its researchers from establishing more than minimum atmospheric lifetimes, and the GWPs based on these lifetimes are therefore also minimums.

Overall, we do not expect that these limitations resulted in large errors in the resulting GWPs; and with the exception of the errors attributable to the last two issues (related to atmospheric lifetimes), we expect that these are random rather than systematic errors. To address the last two issues, we examined the sensitivity of the GWPs of the compounds to atmospheric lifetime. In general, 100-year GWPs for very long-lived compounds are relatively insensitive to increases in assumed atmospheric lifetime, and our analysis confirmed this. However, the 100-year GWPs for the short-lived compounds are sensitive to increases in the assumed atmospheric lifetime. For example, updating the atmospheric lifetime for HFE–7300 based on the currently accepted atmospheric lifetime of methane increases the estimated GWP of HFE–7300 by 10 percent.

Dated: April 1, 2013.

Sarah Dunham,

Director, Office of Atmospheric Programs.

[FR Doc. 2013–07977 Filed 4–4–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9796–4]

Notification of Public Meeting and a Public Teleconference of the Hydraulic Fracturing Research Advisory Panel

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) Science Advisory Board (SAB) Staff Office announces a public meeting and public teleconference of the Hydraulic Fracturing Research Advisory Panel to provide an opportunity for independent expert members of the ad hoc Panel to provide comment on EPA's *Study of the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources: Progress Report,* which was released in December 2012. The meeting will also begin a broader commitment to provide opportunities to brief the panel on the last scientific and technical developments in this emerging topic area.

DATES: The public meeting will be held on Tuesday, May 7, 2013, from 9:30 a.m. to 6:00 p.m. and Wednesday, May 8, 2013, from 8:00 a.m. to 6:00 p.m. (Eastern Daylight Time). The public teleconference will be held on May 16, 2013, from 1:00 p.m. to 5:00 p.m. (Eastern Daylight Time).

ADDRESSES: The public meeting will be held at the Westin Arlington Gateway Hotel located at 801 North Glebe Road, Arlington, VA, 22203. The public teleconference will be conducted by telephone only. The public can also view the May 7–8, 2013 meeting via a non-interactive webcast that will be broadcast on the internet. The connection information to view the meeting via webcast will be provided on the SAB Web site at *http://www.epa.gov/sab* in advance of the meeting.

FOR FURTHER INFORMATION CONTACT: Any member of the public who wants further information concerning the teleconference and meeting may contact Mr. Edward Hanlon, Designated Federal Officer (DFO), EPA Science Advisory Board (1400R), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460; via telephone/voicemail at (202) 564–2134, fax at (202) 565–2098; or email at *hanlon.edward@epa.gov.* General information concerning the SAB can be found on the EPA Web site at *http://www.epa.gov/sab.*

SUPPLEMENTARY INFORMATION:

Background: The SAB was established pursuant to the Environmental Research, Development, and Demonstration Authorization Act (ERDDAA), codified at 42 U.S.C. 4365, to provide independent scientific and technical advice to the Administrator on the technical basis for Agency positions and regulations. The SAB is a Federal Advisory Committee chartered under the Federal Advisory Committee Act (FACA), 5 U.S.C., App. 2. The SAB will comply with the provisions of FACA and all appropriate SAB Staff Office procedural policies. Pursuant to FACA and EPA policy, notice is hereby given that the SAB will hold a public meeting and public teleconference to receive public comments and to provide an opportunity for independent expert members of the SAB Panel to discuss, deliberate, and provide comment on the topics below.

In response to public concern, Congress directed EPA to study the relationship between hydraulic fracturing and drinking water. In 2011, EPA's Office of Research and Development (ORD) published its *Plan to Study the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources.* EPA has requested comment from individual ad hoc panel members on its *Study of the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources* as well as plan future potential activities of the panel. The *Progress Report* describes the status of EPA's ongoing research on the potential

impacts of hydraulic fracturing on drinking water resources.

On August 21, 2012, the SAB Staff Office requested public nominations of experts to serve on a Panel to advise the Agency on EPA's ongoing research on the potential impacts of hydraulic fracturing on drinking water resources (77 FR 50505—50506). On November 27, 2012, the SAB Staff Office posted a notice on the SAB Web site inviting public comments by December 19, 2012, on candidates for the Panel. Information about formation of the Panel can be found at *http://yosemite.epa.gov/sab/sabproduct.nsf/02ad90b136fc21ef85256eba00436459/b436304ba804e3f885257a5b00521b3b!OpenDocument&TableRow=2.1#2*.

The purpose of the May 7–8, 2013, meeting is for individual members of the Panel to provide expert comments on charge questions associated with the research described in EPA's *Progress Report.* The purpose of the May 16, 2013, teleconference is to provide additional opportunity for members of the public to submit relevant oral statements on EPA documents for consideration by the Panel.

Also, periodic opportunities for the public to provide additional input for consideration by the Panel will be provided after the May 7–8, 2013 public meeting and May 16, 2013 public teleconference call.

Availability of Meeting Materials: The agenda and other materials in support of the meeting and teleconference call will be available on the SAB Web site at *http://www.epa.gov/sab* in advance of the meeting and teleconference call.

Procedures for Providing Public Input: Public comment for consideration by EPA's federal advisory committees and panels has a different purpose from public comment provided to EPA program offices. Therefore, the process for submitting comments to a federal advisory committee is different from the process used to submit comments to an EPA program office.

Federal advisory committees and panels, including scientific advisory committees, provide independent advice to the EPA. Members of the public can submit relevant comments for consideration by the Panel. Input from the public to the SAB will have the most impact if it provides specific scientific or technical information or analysis for the SAB to consider or if it relates to the clarity or accuracy of the technical information. Members of the public wishing to provide comment should contact the DFO directly.

Oral Statements: In general, individuals or groups requesting an oral presentation at a public meeting will be limited to five minutes. Persons interested in providing oral statements at the May 7–8, 2013, meeting should contact Mr. Hanlon at the contact information provided above by April 30, 2013. If there is insufficient time during the May 7–8, 2013 public meeting call to allow all scheduled public speakers to provide oral statements, those scheduled public speakers who could not provide oral statements during the May 7–8, 2013 public meeting will be provided opportunity to present their oral statements during a teleconference call scheduled to occur on May 16, 2013.

Written Statements: Written statements for the May 7–8, 2013, meeting and May 16, 2013, teleconference call should be received in the SAB Staff Office by April 30, 2013, so that the information may be made available to the SAB for its consideration prior to this meeting and teleconference call. Written statements should be supplied to the DFO in the following formats: either an electronic copy (preferred), via email (acceptable file format: Adobe Acrobat PDF, MS Word, WordPerfect, MS PowerPoint, or Rich Text files in IBM–PC/Windows 98/2000/XP format), or in hard copy. Submitters are asked to provide electronic versions of each document submitted without signatures, because the SAB Staff Office does not publish documents with signatures on its Web sites. Members of the public should be aware that their personal contact information, if included in any written comments, may be posted to the SAB Web site. Copyrighted material will not be posted without explicit permission of the copyright holder.

Accessibility: For information on access or services for individuals with disabilities, please contact Mr. Hanlon, at the phone number or email address noted above, preferably at least ten days prior to the meeting and teleconference call, to give the EPA as much time as possible to process your request.

Dated: March 25, 2013.

Thomas H. Brennan,

Deputy Director, Science Advisory Board Staff Office.

[FR Doc. 2013–07992 Filed 4–4–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OW–2013–0157; FRL—9798–2]

Petitions to Revise General Permit for U.S. Navy to Transport Vessels for the Purpose of Sinking in Ocean Waters

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of receipt of petitions and opportunity for public comment.

SUMMARY: This notice announces the receipt of and invites public comment on petitions submitted by the Basel Action Network, the Sierra Club, and the Center for Biological Diversity, requesting that the U.S. Environmental Protection Agency take immediate action under the Marine Protection, Research and Sanctuaries Act to protect human health and the environment from polychlorinated biphenyls that leach from ships used for Navy's SINKEX program. The U.S. Environmental Protection Agency invites public comment on the aforementioned petitions for the purpose of determining how to respond to the requests for action related to the Marine Protection, Research and Sanctuaries Act.

DATES: Comments must be received on or before May 6, 2013.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OW–2013–0157, by one of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the on-line instructions for submitting comments.

Mail: Send an original and three copies of your comments and enclosures (including references) to EPA Water Docket, U.S. Environmental Protection Agency, Mail Code: 2822–IT, 1200 Pennsylvania Avenue NW., Washington, DC 20460, Attention Docket No. EPA–HQ–OW–2013–0157.

Hand delivery: EPA Water Docket, EPA Docket Center, EPA West Building, Room 3334, 1301 Constitution Avenue NW., Washington, DC 20460, Docket No. EPA–HQ–OW–2013–0157. Deliveries to the docket are accepted only during their normal hours of operation: 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. For access to docket materials, call: (202) 566–2426, to schedule an appointment.

E-mail: ow-docket@epa.gov; Attention Docket No. EPA–HQ–OW–2013–0157. To ensure that EPA can properly respond to comments, commenters should cite the paragraph(s) or sections in the proposed permit to which each

comment refers. Commenters should use a separate paragraph for each issue discussed, and must submit any references cited in their comments. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment. Electronic files should avoid any form of encryption and should be free of any defects or viruses.

Instructions: Direct your comments to docket ID number EPA–HQ–OW–2013–0157. 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 *http://www.regulations.gov* or email. The Federal *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 email comment directly to EPA without going through *http://www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the 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 EPA Water Docket are listed in the docket index. Although listed in the index, certain 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 EPA Water Docket in Room 3334, 1301 Constitution Avenue (EPA West Building), NW., Washington, DC 20004. The hours of operation of this Docket Facility are from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the EPA Water Docket is (202) 566–2426.

FOR FURTHER INFORMATION CONTACT:

Laura S. Johnson, Marine Pollution Control Branch (4504T), U.S. EPA, 1200 Pennsylvania Avenue NW., Washington, DC 20460; (202) 566–1273; *johnson.laura-s@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Interested Entities

Category	Examples of interested entities
Federal Government	U.S. Navy, Maritime Administration, U.S. Army Corps of Engineers, U.S. Coast Guard, National Oceanic and Atmospheric Administration.
State/Local/Tribal Government	Coastal communities.
Industry and General Public	Shipyards, salvage companies, environmental remediation enterprises, commercial and recreational deep sea fishing interests, environmental interest groups.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be interested in this notice. This table lists the types of entities that EPA is now aware could potentially be interested in this notice. Other types of entities not listed in the table could also be interested.

B. What should I consider as I prepare my comments for EPA?

Consider the following suggestions for preparing your comments:

1. Identify the docket identification number in the subject line on the first page of your response. Also, it would be helpful to EPA if you provided the name, date, and **Federal Register** citation related to your comments.
2. Explain your views as clearly as possible, including the subject matter about which you agree or disagree and why.
3. Describe any assumptions that you used.
4. Provide any technical information and/or data you used that support your views.
5. If you estimate potential burden or costs, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
6. Provide specific examples to illustrate your concerns.
7. Offer alternatives.
8. Make sure to submit your comments by the comment period deadline identified.

II. Background

The Marine Protection, Research and Sanctuaries Act (MPRSA) of 1972, as amended, also known as the Ocean Dumping Act, regulates the transportation and dumping of material into ocean waters. Under the MPRSA, no permit may be issued for ocean dumping where such dumping will unreasonably degrade or endanger human health or the marine environment.

In 1977, the U.S. Environmental Protection Agency (EPA) promulgated regulations for implementing the MPRSA permitting authority, 40 C.F.R. parts 220–229. 42 FR 2489 (Jan. 11, 1977). At that time, EPA issued a general permit to the U.S. Navy (Navy) for the Sink Exercise Program (SINKEX) to transport vessels from the United States, or from any other location, for the purpose of sinking such vessels in ocean waters in testing ordnance and providing related data. 40 C.F.R. 229.2. SINKEX involves the use of obsolete military vessels for target practice by military personnel, with the consequent sinking of the vessel. The Navy views these activities as essential for training personnel and testing military equipment. Vessels used for SINKEX are prepared according to the terms of the MPRSA general permit issued to the Navy.

Under the MPRSA general permit, obsolete vessels used in SINKEX are required to be sunk at least 50 nautical miles from land and at depths of at least 1000 fathoms (6000 feet). The permit requires that, prior to sinking, appropriate measures be taken to remove to the maximum extent practicable all materials that may degrade the marine environment. This includes the emptying of all fuel tanks and fuel lines to the lowest point

practicable (followed by flushing with water and again emptying) and removing from the hulls other pollutants and all readily detachable materials capable of creating debris or contributing to chemical pollution. Thus, while the permit requires appropriate measures to remove to the maximum extent practicable all materials that may degrade the marine environment, the permit also recognizes that it may be impracticable to remove some materials.

In a letter dated August 2, 1999 from EPA to the Navy, EPA provided its interpretation of the MPRSA general permit requirement to ''remove to the maximum extent practicable all materials that may degrade the marine environment'' as including polychlorinated biphenyls (PCB) containing materials, such as ship components containing PCBs. See Letter from Robert H. Wayland, Director of the Office of Wetlands, Oceans and Watersheds, to Elsie L. Munsell, Deputy Assistant Secretary of the Navy (Aug. 2, 1999). This letter states that:

> Before engaging in a SlNKEX, the Navy must conduct an inventory of each SINKEX vessel to ascertain the presence of PCBs. This inventory and list of items removed prior to sinking must be provided to EPA in the annual report * * *. Before sinking a SINKEX vessel, qualified personnel at a Navy or other approved facility shall:
>
> —Remove all transformers containing 3 pounds or more of dielectric fluid and all capacitors containing 3 pounds or more of dielectric fluid.
>
> —Use all reasonable efforts to remove any capacitors and transformers containing less than 3 pounds of dielectric fluid from the vessel. Reasonable efforts include, but are not necessarily limited to, the removal of capacitors from electrical and control panels by using hand tools such as wire or bolt cutters or a screw driver.
>
> —Drain and flush hydraulic equipment, heat transfer equipment, high/low pressure systems, cutting power machinery which uses cooling or cutting oil, and containers containing liquid PCBs at greater than or equal to 50 parts per million (ppm).

In the August 2, 1999 letter from EPA to the Navy, EPA noted that ''it is often practicable to remove non-liquid PCB-containing materials, including: air handling system gaskets; rubber; plastic; dried applied paint that is flaked-off; electrical cable insulation; and other non-liquid coatings and material, before sinking the vessel.'' To the extent that their removal is practicable, EPA explained that ''these non-liquid PCB-containing materials are required to be removed under the MPRSA permit. However, when such objects cannot be practicably removed or their removal threatens the structural integrity of the vessels so as to impede the SINKEX, the Navy may leave such items in place (e.g., felt materials that are bonded in bolted flanges or mounted under heavy equipment, certain paints, and adhesives).'' EPA further noted that ''objects may be considered not capable of practicable removal if equipment must be disassembled or removed for access to the objects, if the objects must be removed by heat, chemical stripping, scraping, abrasive blasting or similar process, or if removal would endanger human safety or health even when conducted with protective equipment and reasonable safety measures.'' Further, the August 2, 1999 letter states that the Navy shall report annually to EPA, the effort taken to clean each vessel prior to SINKEX and provide an estimate of the weight of PCBs present onboard at the time of sinking.

III. Today's Action

EPA is providing the opportunity for public comment on the two petitions received that request EPA amend the MPRSA general permit as it relates to removal of PCBs from ships used in Navy's SINKEX program. The first petition, dated June 2011, and submitted by the Sierra Club and the Basel Action Network, requested that EPA:

> Amend the MPRSA general permit for SINKEX to comply with the MPRSA by reflecting the latest scientific knowledge about the amount of PCBs disposed through the SINKEX program and about leaching of PCBs from sunken ships. At a minimum, the permit should be amended to require:
>
> a. Materials containing PCBs to be removed from ships to the ''maximum extent practicable'' with the best current techniques; and
>
> b. Prior to sinking, remediate ships to the London Convention's ''trace contaminant'' requirement.

The second petition, dated April 2012, and submitted by the Basel Action Network, Sierra Club, and the Center for Biological Diversity, again requested that EPA amend the existing MPRSA permit for SINKEX:

> 1. Effective immediately, requiring all PCB-contaminated materials in concentrations of 50 ppm or greater to be removed from SINKEX vessels prior to sinking;
>
> 2. Requiring all PCB-contaminated materials in concentrations of less than 50 ppm to be removed from SINKEX vessels prior to sinking to the maximum extent practicable; and
>
> 3. Requiring additional studies to determine whether PCB-contaminated materials in concentrations of less than 50 ppm constitute ''trace'' contaminants, such that their dumping will not cause undesirable effects including the possibility of bioaccumulation. Such additional studies should include the most recent data on the toxicity, persistence, and bioaccumulation of PCBs and should include monitoring at multiple recent sink sites. Studies should also assess the releases of other potentially hazardous pollutants into the marine environment from the SINKEX program including heavy metals, asbestos and radioactive substances.

Technical studies and data that accompanied the petitions are included in the docket for this proceeding. As noted above, EPA has not made the copyrighted material available on the Internet, but that material is publicly available in hard copy form via the Public Reading Room in EPA's Docket Center.

Dated: March 28, 2013.

Nancy Stoner,

Acting Assistant Administrator, Office of Water.

[FR Doc. 2013–07988 Filed 4–4–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2012–0902; FRL–9382–9]

Polychlorinated Biphenyls (PCBs); Recycling Plastics from Shredder Residue

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is announcing an interpretation of its regulations that will generally allow for the recycling of plastic separated from shredder residue under the conditions described in the Voluntary Procedures for Recycling Plastics from Shredder Residue, relying principally on the regulatory provisions for excluded PCB products. The interpretation described in this notice responds to questions EPA has received about the applicability of the excluded PCB products regulations.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPPT–2012–0902, is available at *http://www.regulations.gov* or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Please review the visitor instructions and additional information

about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Peter Gimlin, National Program Chemicals Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 566–0515; email address: *gimlin.peter@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

This notice is directed to the public in general, and may be of interest to a wide range of stakeholders, including private citizens, Federal, tribal, state and local governments, environmental consulting firms, industry representatives, environmental organizations and other public interest groups. Since others may also be interested, the Agency has not attempted to describe all the specific entities that may have interest in this notice. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

EPA is interpreting its regulations to generally allow for recycling of plastic separated from shredder residue under the conditions described in the Voluntary Procedures for Recycling Plastics from Shredder Residue (Ref. 1), relying principally on the regulatory provision for excluded PCB products at 40 CFR part 761.

II. Background

EPA was approached by the Institute of Scrap Recycling Industries, Inc. (ISRI), regarding separation, recycling, use, and distribution of recycled plastics from shredder residue recovered from metals recycling facilities (referred to by ISRI as automobile shredder residue (ASR) aggregate). In a February 24, 2011 letter, ISRI requested ''written confirmation that separating plastics from ASR aggregate for use and distribution in commerce, using processes that reduce any PCBs that may be present to a level at or below which there is no unreasonable risk, is authorized'' under regulations promulgated pursuant to the Toxic Substances Control Act (TSCA) (see 16 U.S.C. 2605(e)) (Ref. 2). ISRI stated that:

* * * analysis shows that the separation, recycling, distribution in commerce, and reuse of plastics from shredder aggregate is consistent with existing authorizations that allow the use and distribution in commerce of products that contain low levels of PCBs, including provisions for ''excluded PCB products'' and ''excluded PCB manufacturing processes'' (as defined in 40 CFR 761.3).

ISRI also stated that resolving regulatory uncertainty could lead to investments and further development in innovative methods to separate plastics from ASR aggregate that would produce broad environmental benefits and increase global competitiveness (Ref. 2).

ISRI developed a set of voluntary procedures designed to prevent the introduction of PCBs that are regulated for disposal into recycled plastics recovered from shredder residue generated by metal recycling facilities. The Voluntary Procedures for Recycling Plastics from Shredder Residue (Ref. 1) includes development and implementation of a documented materials management system through:

1. Documented source control programs aimed at preventing the introduction of PCBs regulated for disposal into the shredder feedstock materials that contribute to any shredder residue from which plastics will be recovered for recycling; and

2. Documented output control programs for facilities processing producing/recycling plastics from shredder residue. The Voluntary Procedures for Recycling Plastics from Shredder Residue and supporting materials are available in the docket at docket ID number EPA–HQ–OPPT–2012–0902.

On December 12, 2012, EPA published a notice of request for public comments in the **Federal Register**, entitled Polychlorinated Biphenyls (PCBs); Recycling Plastics From Shredder Residue (77 FR 74006). Additional background information on recycling activities that would be affected by this interpretation, including potential environmental and economic benefits, is provided in the December 12, 2012 notice and supporting materials are available in the docket at docket ID number EPA–HQ–OPPT–2012–0902. In response to this notice, 27 unique public comment submissions were received by the Agency. Of these, some 23 were supportive of the interpretation the Agency explained in the notice. In general, these commenters emphasized the environmental and economic benefits that recycling of plastic from shredder residue would provide, and concurred with EPA's assessment of the facts and interpretation of the PCB regulations as they applied to shredder residue and the use of plastics recovered from that residue. Two submissions, including a consolidated submission submitted on behalf of nine environmental organizations, objected to the Agency's adoption of this interpretation on a number of points, such as environmental justice, the adequacy of the underlying data and analysis, as well as the legal basis for the Agency's interpretation. Finally, one commenter suggested changes to the Voluntary Procedures for Recycling Plastics from Shredder Residue and another commenter submitted an administrative request regarding the comment period. All public comments received in response to the notice are available in the docket, as is a Response to Comments Document developed by EPA (Ref. 3). After review and consideration of the comments received, EPA has decided to adopt the interpretation discussed in the December 12, 2012 notice and summarized in Unit III. of this notice.

III. Summary of Interpretation

The interpretation will generally allow for the recycling of plastic separated from shredder residue under the conditions described in the Voluntary Procedures for Recycling Plastics from Shredder Residue (Ref. 1), relying principally on the regulatory provisions for excluded PCB products.

TSCA section 6(e) generally prohibits the manufacture, processing, distribution in commerce and use of PCBs. However, EPA has by regulation excluded certain materials, including excluded PCB products, from these prohibitions. Excluded PCB products are defined as follows:

Excluded PCB products means PCB materials which appear at concentrations less than 50 ppm, including but not limited to:

(1) Non-Aroclor inadvertently generated PCBs as a byproduct or impurity resulting from a chemical manufacturing process.

(2) Products contaminated with Aroclor or other PCB materials from historic PCB uses (investment casting waxes are one example).

(3) Recycled fluids and/or equipment contaminated during use involving the products described in paragraphs (1) and (2) of this definition (heat transfer and hydraulic fluids and equipment and other electrical equipment components and fluids are examples).

(4) Used oils, provided that in the cases of paragraphs (1) through (4) of this definition:

(i) The products or source of the products containing < 50 ppm concentration PCBs were legally manufactured, processed, distributed in commerce, or used before October 1, 1984.

(ii) The products or source of the products containing < 50 ppm concentrations PCBs were legally manufactured, processed, distributed in commerce, or used, i.e., pursuant to authority granted by EPA regulation, by exemption petition, by settlement agreement, or pursuant to other Agency-approved programs;

(iii) The resulting PCB concentration (i.e. below 50 ppm) is not a result of dilution, or

leaks and spills of PCBs in concentrations over 50 ppm.

40 CFR 761.3.

EPA regulations allow the use, processing, and distribution in commerce of excluded PCB products. 40 CFR 761.20(a) and (c). Except as otherwise provided, the regulations do not restrict the forms of use, processing and distribution that are allowed. EPA specifically identified, as one likely source of PCBs in excluded PCB products, ''contamination during recycling activities involving'' historic PCBs. 52 FR 25838, 25844 (July 8, 1987). EPA believes that it is reasonable to interpret the regulations as generally allowing the recycling of excluded PCB products. Accordingly, under the interpretation, to the extent that the feedstock (scrap materials) to a shredder consists of these kinds of materials, the plastics separated from the resulting residue can be recycled (and the resulting recycled product is also an excluded PCB product that can be processed, used and distributed in commerce, including being further recycled), provided the PCB concentration in any resulting product is below 50 parts per million (ppm).

The burden of demonstrating that a regulatory exclusion applies rests with the party seeking that exclusion. EPA believes that, for shredders and their suppliers that follow the Voluntary Procedures for Recycling Plastics from Shredder Residue, it is appropriate to generally treat the feedstock as consisting of excluded PCB products unless there is information specifically indicating that the feedstock does not qualify. If shredders and suppliers do not follow the Voluntary Procedures for Recycling Plastics from Shredder Residue, they will need to be able to otherwise demonstrate that the feedstock and residue meet the exclusion. Clearly if the feedstock materials or residue contain PCBs at concentrations ≥ 50 ppm, the materials cannot qualify as excluded PCB products.

EPA acknowledges uncertainty as to the source of the PCBs in shredder residue. However, EPA believes the procedures, as explained in the Voluntary Procedures for Recycling Plastics from Shredder Residue, can prevent the introduction of PCBs at levels ≥ 50 ppm. EPA may periodically evaluate the processes and procedures involved in recycling plastics recovered from shredder residue. In addition, EPA believes it is likely that the number of potential sources of PCBs at levels ≥ 50 ppm has declined since the TSCA section 6(e) prohibitions went into effect. If PCBs in the feedstock material are < 50 ppm, it is plausible that the sources of PCBs in the residue are excluded PCB products. The information available to EPA indicates that the PCBs found associated with plastics separated from residue are Aroclor PCBs. Aroclors were intentionally manufactured PCB mixtures, not inadvertently generated PCBs. Since PCBs in general and Aroclors more specifically have not been intentionally produced in the United States since the prohibitions in TSCA section 6(e) became effective, the Aroclor identity of the PCBs found associated with plastics separated from shredder residue suggests that they were manufactured prior to 1984.

In promulgating the excluded PCB product rule, EPA described the provision as follows: EPA is adopting the generic 50 ppm exclusion for the processing, distribution in commerce, and use, based on the Agency's determination that the use, processing, and distribution in commerce of products with less than 50 ppm PCB concentration will not generally present an unreasonable risk of injury to health or the environment. EPA could not possibly identify and assess the potential exposures from all the products which may be contaminated with PCBs at less than 50 ppm. * * * EPA has concluded that the costs associated with the strict prohibition on PCB activities are large and outweigh the risks posed by these activities. 53 FR 24210 (June 27, 1988).

EPA has further stated, with respect to the excluded PCB products rule: ''These amendments have excluded the majority of low-level PCB activities (less than 50 ppm) from regulation'' (Ref. 4). Given the difficulty of determining the precise source of PCBs, EPA believes the purpose of excluding ''old'' PCBs under the excluded products rule is best effectuated in these circumstances by treating < 50 ppm materials entering a shredder as excluded PCB products unless there is information specifically indicating that the materials do not qualify.

After reviewing the comments received, EPA has weighed the competing considerations and decided to adopt, through this notice, the interpretation discussed in the December 12, 2012 notice. 77 FR 74006 (December 12, 2012). This interpretation is not a legislative rule because it does not impose any binding requirements on either EPA or the regulated community.

IV. References

As indicated under **ADDRESSES**, a docket has been established for this notice under docket ID number EPA–HQ–OPPT–2012–0902. The following is a listing of the documents that are specifically referenced in this notice. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

1. ISRI. Voluntary Procedures for Recycling Plastics from Shredder Residue, October 24, 2012.

2. ISRI. Letter from Robin K. Weiner to Steve Owens, February 24, 2011.

3. EPA. Agency Response to Comments—Polychlorinated Biphenyls (PCBs); Recycling Plastics From Shredder Residue, March 2013.

4. EPA. PCB Q & A Manual: An EPA TSCA assistance document designed to provide the regulated community with Agency interpretations to frequently posed questions, 1994, available at *http://www.epa.gov/osw/hazard/tsd/pcbs/pubs/manual.pdf.*

List of Subjects

Environmental protection, Hazardous substance, PCBs, Plastic, Polychlorinated biphenyls, Recycling, Shredder residue.

Dated: March 29, 2013.

James Jones,

Acting Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2013–07981 Filed 4–4–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9798–9]

Notice of Proposed CERCLA Agreement and Order on Consent for Removal Action by Bona Fide Prospective Purchaser; All Metals Processing Company Site, San Fernando Valley Area 2 Superfund Site, Glendale Chromium Operable Unit, 264 W. Spazier Ave., Burbank, California

ACTION: Notice; request for public comment.

SUMMARY: Notice is hereby given pursuant to Section 122(i), of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as Amended (CERCLA) that the United States Environmental Protection Agency (EPA) has reached a

proposed agreement (Agreement) with a Bona Fide Prospective Purchaser concerning a removal action to carried out at the All Metal Processing Company Site, part of the San Fernando Valley Area 2 Superfund Site, Glendale Chromium Operable Unit, located at 264 W. Spazier Ave., Burbank, California. Under the proposed Agreement, executed March 25, 2013, the Brett and Chris Warner Trust, dated May 31, 2012 (Purchaser), the Bona Fide Prospective Purchaser of 264 W. Spazier Ave., Burbank, California, has agreed to relocate an existing monitoring well on the property under the oversight of the EPA. In addition, the Purchaser has agreed to maintain a cap over the property through construction of a warehouse and adjacent parking area. In addition, the Purchaser has agreed to pay EPA its oversight costs up to $20,000. In return, the Purchaser will receive a covenant not to sue by EPA, provided the Purchaser complies with all terms and conditions of the Agreement. The Purchaser will also receive contribution protection under CERCLA.

For thirty (30) calendar days following the date of publication of this notice, EPA will receive comments relating to the proposed Agreement. EPA's response to comments received will be available for public inspection at the Superfund Records Center, 95 Hawthorne Ave., Suite 403S, San Francisco, CA 94105, 415–764–4963.

DATES: Comments must be received on or before May 6, 2013.

Availability: The proposed Agreement may be obtained from the Superfund Records Center, 95 Hawthorne Street, Suite 403S, San Francisco, CA 94105, Phone 415–764–4963. Comments regarding the proposed Agreement should be addressed to Larry Bradfish at the address below, and should reference ''All Metals Processing Company Site'' and ''EPA Docket No. R9–2013–04.''

FOR FURTHER INFORMATION CONTACT: Larry Bradfish, Assistant Regional Counsel (ORC–3), Office of Regional Counsel, U.S. EPA Region IX, 75 Hawthorne Street, San Francisco, CA 94105; Email: *bradfish.larry@epa.gov;* Phone (415) 972–3934.

Dated: March 28, 2013.

Jane Diamond,

Director, Superfund Division, Region IX.

[FR Doc. 2013–07989 Filed 4–4–13; 8:45 am]

BILLING CODE 6560–50–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 April 22, 2013.

A. Federal Reserve Bank of Atlanta (Chapelle Davis, Assistant Vice President) 1000 Peachtree Street NE., Atlanta, Georgia 30309:

1. *Phillip Bruce Culpepper, Tallahassee, Florida; Richard Rene Dostie, Charles Eldridge Hughes, Jr., and Jan Malcolm Jones, Jr., all of Jacksonville, Florida; James Thomas Katsur, Longwood, Florida; William Andrew Krusen, Jr., and Allan Scott Martin, both of Tampa, Florida; Linda Claire McGurn, Micanopy, Florida; and Manuel Gonzalo Sanchez,* Gainesville, Florida; to collectively acquire voting shares of Florida Capital Group, Inc., and thereby indirectly acquire voting shares of Florida Capital Bank, both of Jacksonville, Florida.

B. Federal Reserve Bank of Minneapolis (Jacqueline G. King, Community Affairs Officer) 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. *William P. Von Holtum, Edina, Minnesota, individually and as trustee of the voting trust of the John E. Von Holtum Estate; Megan E. Von Holtum and Christopher J. Von Holtum,* all of Edina, Minnesota, as members of the Von Holtum Family Group; to retain voting shares of Central Trust Company, Edina, Minnesota, and thereby indirectly retain voting shares of Central Bank and Trust, Lander, Wyoming; CenBank, Buffalo Lake, Minnesota; and VH Bancorporation, Inc., Edina, Minnesota, and its subsidiary Grand Marais State Bank, Grand Marais, Minnesota.

2. *Tina Pogatchnik Rabe,* Hinckley, Minnesota; as a member of the Pogatchnik family group, and individually and as trustee of the D.A. Pogatchnik Family Trust, and the Bruce Pogatchnik Family Trust, both in Hinckley, Minnesota, and Bruce A. Pogatchnik, as trustee of the Dean L. Pogatchnik Grandchildren's Trust, Finlayson, Minnesota, and for all to join the Pogatchnik family group; to retain voting shares of Finlayson Bancshares, Inc., Finlayson, Minnesota, and thereby indirectly retain voting shares of Northview Bank, Sandstone, Minnesota, and First Independent Bank, Russell, Minnesota.

Board of Governors of the Federal Reserve System, April 2, 2013.

Margaret McCloskey Shanks,

Deputy Secretary of the Board.

[FR Doc. 2013–07952 Filed 4–4–13; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than April 19, 2013.

A. Federal Reserve Bank of Richmond (Adam M. Drimer, Assistant Vice President) 701 East Byrd Street, Richmond, Virginia 23261–4528:

1. *Hope Holding Connell,* Raleigh, North Carolina; to retain voting shares of Southern BancShares (N.C.), Inc., and thereby indirectly retain voting shares of Southern Bank and Trust, both in Mount Olive, North Carolina.

Board of Governors of the Federal Reserve System, April 1, 2013.

Margaret McCloskey Shanks,

Deputy Secretary of the Board.

[FR Doc. 2013–07886 Filed 4–4–13; 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 applications will also 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 April 29, 2013.

A. Federal Reserve Bank of Dallas (E. Ann Worthy, Vice President) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. *Hillister Enterprises, II, Inc., Umphrey II Family Limited Partnership, and CBFH, Inc.,* all of Beaumont, Texas; to acquire voting shares of and merge with VB Texas, Inc., and thereby indirectly acquire voting shares of Vista Bank Texas, Houston, Texas.

Board of Governors of the Federal Reserve System, April 1, 2013.

Margaret McCloskey Shanks,

Deputy Secretary of the Board.

[FR Doc. 2013–07885 Filed 4–4–13; 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 applications will also 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 May 2, 2013.

A. Federal Reserve Bank of Minneapolis (Jacqueline G. King, Community Affairs Officer) 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. *J & B Financial Holdings, Inc.,* Minneapolis, Minnesota; to become a bank holding company by acquiring 100 percent of the voting shares of Mills Resolute Bank, Sanborn, Minnesota.

Board of Governors of the Federal Reserve System, April 2, 2013.

Margaret McCloskey Shanks,

Deputy Secretary of the Board.

[FR Doc. 2013–07953 Filed 4–4–13; 8:45 am]

BILLING CODE 6210–01–P

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090–0289; Docket 2012–0001; Sequence 18]

Information Collection; Tangible Personal Property Report (SF–428A, 428B, and 428C)

AGENCY: Office of Governmentwide Policy, General Services Administration (GSA).

ACTION: Notice of request for comments regarding an extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Office of Governmentwide Policy will submit to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement concerning reporting tangible personal property.

In support of OMB's continuing effort to reduce paperwork and respondent burden, GSA invites the general public and other Federal agencies to take this opportunity to comment on the proposed information collection. In accordance with the Paperwork Reduction Act of 1995, this notice seeks comments concerning forms that will be used to collect information related to tangible personal property when required by a Federal financial assistance award. To view the form, go to OMB's main Web page at *www.OMB.gov* and click on the ''Grants Management'' and ''Forms'' links. OMB specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: *Comment Due Date:* June 4, 2013.

FOR FURTHER INFORMATION CONTACT: Michael Nelson, Chair, Post-Award Workgroup; telephone 202–482–4538; fax 301–713–0806; email *Michael.Nelson@noaa.gov;* mailing address 1305 East-West Highway, Room 7142, Silver Spring, MD 20910.

ADDRESSES: Submit comments identified by Information Collection 3090–0289, Tangible Personal Property Report, by any of the following methods:

- *Regulations.gov: http://www.regulations.gov.*

Submit comments via the Federal eRulemaking portal by searching the OMB control number. Select the link ''Submit a Comment'' that corresponds with ''Information Collection 3090–0289, Tangible Personal Property Report.'' Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''Information Collection 3090–0289,

Tangible Personal Property Report'' on your attached document.

- *Fax:* 202–501–4067.
- *Mail:* General Services Administration, Regulatory Secretariat (MVCB), 1275 First Street NE., Washington, DC 20417. ATTN: Hada Flowers/IC 3090–0289, Tangible Personal Property Report.

Instructions: Please submit comments only and cite Information Collection 3090–0289, Tangible Personal Property Report, in all correspondence related to this collection. All comments received will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided.

SUPPLEMENTARY INFORMATION:

A. Purpose

GSA, on behalf of the Federal Grants Streamlining Initiative, proposes to renew a standard form, the Tangible Personal Property Report (SF–428). The SF–428 includes a cover page, an Annual Report attachment, a Final Report attachment, a Disposition/Request Report attachment and a Supplemental Sheet to provide detailed item information. The purpose of this form is to provide a standard form for assistance recipients to use when they are required to provide a Federal agency with information related to federally owned property, or equipment and supplies (tangible personal property) acquired with assistance award funds. The form does not create any new reporting requirements. It does establish a standard annual reporting date of September 30 to be used if an award does not specify an annual reporting date. The standard form will replace any agency unique forms currently in use to allow uniformity of collection and to support future electronic submission of information.

Background

Public Law 106–107 requires OMB to direct, coordinate, and assist Executive Branch departments and agencies in establishing an interagency process to streamline and simplify Federal financial assistance procedures for non-Federal entities. The law also requires executive agencies to develop, submit to Congress, and implement a plan for that streamlining and simplification. Twenty-six Executive Branch agencies jointly submitted a plan to the Congress in May 2001. The plan described the interagency process through which the agencies would review current policies and practices and seek to streamline and simplify them. The process involved interagency work groups under the auspices of the U.S. Chief Financial Officers Council, Grants Policy Committee. The plan also identified substantive areas in which the interagency work groups had begun their review. Those areas are part of the Federal Grants Streamlining Initiative.

This proposed form is an undertaking of the interagency Post-Award Workgroup that supports the Federal Grants Streamlining Initiative. Additional information on the Federal Grants Streamlining Initiative, which focuses on implementing the Federal Financial Assistance Management Improvement Act of 1999 (Pub. L. 106–107), is set forth in the **Federal Register** published on September 13, 2006 (71 FR 54098). An overview of the SF–428 and five other report forms being developed under the Initiative was provided during a webcast of the Grants Policy Committee of the U.S. Chief Financial Officers Council held on March 8, 2007 (72 FR 7090, February 14, 2007).

Under the standards for management and disposition of federally-owned property, equipment and supplies (tangible personal property) in 2 CFR part 215, the ''Uniform Administrative Requirements for Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations,'' and the ''Uniform Administrative Requirements for Grants and Agreements with State and Local Governments,'' codified by Federal agencies at 53 FR 8048, March 11, 1988, recipients may be required to provide Federal agencies with information concerning property in their custody annually, at award closeout or when the property is no longer needed. During the public consultation process mandated by Public Law 106–107, recipients suggested the need for clarification of these requirements and the establishment of a standard form to help them submit appropriate property information when required. The Tangible Personal Property Report (SF–428) must be used in connection with requirements listed in the table below and Federal awarding agency guidelines:

For * * *	A recipient must * * *	When * * *	Under * * *
Federally owned property	Submit an inventory listing	Annually, with information accurate as of 30 September, unless the award specifies a different date.	2 CFR 215.33(a)(1) A–102, ___.32(f)(2)
	Request Federal agency authorization.	It wants to use the property on other activities not sponsored by the Federal Government.	2 CFR 215.34(d)
	Notify the Federal awarding agency.	Immediately upon finding property is lost, damaged, or stolen.	2 CFR 215.33(f)(4)
	Request disposition instructions.	The property is no longer needed	2 CFR 215.33(a)(1) A–102, ___.32(f)(3)
		Upon completion of the award	2 CFR 215.33(a)(1) and 2 CFR 215.71(f) A–102, ___.50(b)(5)
Grantee-acquired equipment in which the Federal Government retains an interest.	Obtain the approval of the Federal awarding agency.	Acquiring replacement equipment, before: ..... (1) using the current equipment as trade-in; or ..... (2) selling it and using the proceeds to offset the costs of the replacement equipment.	2 CFR 215.34(e) A–102, ___.32(c)(4)
	Compensate the original Federal awarding agency or its successor.	Equipment has a per unit fair market value of greater than $5,000 and the grantee no longer needs the equipment for Federally supported activities and retains the equipment for other uses.	2 CFR 215.34(g) A–102, ___.32(e)(2)
	Request disposition instructions.	It no longer needs the equipment for any purpose	2 CFR 215.34(g)

For * * *	A recipient must * * *	When * * *	Under * * *
	Sell the equipment and reimburse the Federal awarding agency for the Federal share.	Equipment has a per unit fair market value of greater than $5,000 and the recipient no longer needs the equipment for any purpose and requested disposition instructions, and either was instructed to sell the equipment or received no instructions within 120 days.	2 CFR 215.34(g)(1) A–102, ___.32(e)(2)
	Account for the equipment	Upon completion of the award, when the awarding agency has reserved the right to transfer title to the Federal Government or a third party.	2 CFR 215.71(f) and 2 CFR 215.34(g)(4)(ii)
Supplies	Compensate the Federal Government for its share.	It has a residual inventory of unused supplies exceeding $5,000 in aggregate value at the end of a project or program that is not needed for other Federally supported activities.	2 CFR 215.35(a) A–102, ___.33(b)

B. Annual Reporting Burden

This report will be used to collect information related to tangible personal property (equipment and supplies) when required by a Federal financial assistance award. The Tangible Personal Property Report (SF–428) was posted to the OMB MAX Web site. Fourteen agencies posted annual burden estimates. The estimated total annual burden hours are 33,346.5. A listing with the number of respondents, the number of responses per respondent and average burden per hour per recipient by agency follows.

Respondents: Federal agencies and their assistance recipients.

Estimated Total Annual Burden Hours: 33,346.5

Estimated Cost: There is no expected cost to the respondents or to agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Agency	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Tangible Personal Property Report (TPPR) and Attachments	DOE	750	1.5	2.75	3,094
Tangible Personal Property Report (TPPR) and Attachments	EPA	300	1	2	600
Tangible Personal Property Report (TPPR) and Attachments	DOD	300	1	2.75	825
Tangible Personal Property Report (TPPR) and Attachments	SSA	125	1	2	250
Tangible Personal Property Report (TPPR) and Attachments	IMLS	1000	1.5	2	3,000
Tangible Personal Property Report (TPPR) and Attachments	DOC	130	1	2	260
Tangible Personal Property Report (TPPR) and Attachments	DHS	972	1.5	2.75	4,009.5
Tangible Personal Property Report (TPPR) and Attachments	HHS OPDIVs	7681	1	2	15,362
Tangible Personal Property Report (TPPR) and Attachments	HUD	4158	1	1.43	5,946
Tangible Personal Property Report (TPPR) and Attachments	NEA	0	0	0	0
Tangible Personal Property Report (TPPR) and Attachments	NEH	0	0	0	0
Tangible Personal Property Report (TPPR) and Attachments	ED	0	0	0	0
Tangible Personal Property Report (TPPR) and Attachments	VA	0	0	0	0

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (MVCB), 1275 First Street NE., Washington, DC 20417, telephone (202) 501–4755. Please cite OMB Control No. 3090–0289, Tangible Personal Property Report, in all correspondence.

Dated: March 27, 2013.

Casey Coleman,

Chief Information Officer.

[FR Doc. 2013–07965 Filed 4–4–13; 8:45 am]

BILLING CODE 6820–RH–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics, Population Health Subcommittee: Meeting

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS), Subcommittees on Population Health and Privacy, Confidentiality & Security.

Time and Date: April 30, 2013–May 2, 2013, 9:00 a.m.–5:00 p.m. EST.

Place: National Center for Health Statistics, 3311 Toledo Road, Hyattsville, MD 20782, Tel: 1–301–458–4200.

Status: Open.

Purpose: The purpose of this meeting is to provide an opportunity for the Population Health and Privacy, Confidentiality and Security Subcommittees to hear from data providers, users, and experts in health data on community uses of data to improve health. NCVHS seeks to: (1) Advance its understanding of access to and use of data by communities to improve population health; (2) refine its Stewardship Framework for the Use of Community Health to support the needs of various types of community initiatives; and (3) better understand the role of government in providing data, tools, and resources to promote community driven change.

The agenda is organized for attendees to participate in breakout groups throughout the day exploring such topics and themes as ''How best to promote community engagement and participation,'' ''How to promote secure practices,'' ''How to achieve information-enabled community-driven change,'' ''What is the need for standardized approaches for generating qualitative information,'' and ending with ''What analytic support can state and the Federal government provide.'' Participants will be briefed on the results of a preliminary environmental scan of programs supporting local community data use as well as key messages from the Committee's report: the Community as a Learning System: Using Local Data to Improve Local Health. *http://www.ncvhs.hhs.gov/111213chip.pdf.*

Contact Person for More Information: Marjorie S. Greenberg, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Room 2402, Hyattsville, Maryland 20782, telephone (301) 458–4245 or Maya Bernstein, lead staff for the Privacy, Confidentiality & Security Subcommittee, NCVHS, Hubert H. Humphrey Building, Department of Health & Human Services, 200 Independence Ave SW., Washington, DC 20201, Telephone (202) 690–5896. Program information as well as summaries of meetings and a roster of committee members are available on the NCVHS home page of the HHS Web site: *http://www.ncvhs.hhs.gov/*, where further information including an agenda will be posted when available.

Should you require reasonable accommodation, please contact the CDC Office of Equal Employment Opportunity on (301) 458–4EEO (4336) as soon as possible.

Dated: March 28, 2013.

James Scanlon,

Deputy Assistant Secretary for Planning and Evaluation, Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 2013–08025 Filed 4–4–13; 8:45 am]

BILLING CODE 4151–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Meeting of the Presidential Commission for the Study of Bioethical Issues

AGENCY: Presidential Commission for the Study of Bioethical Issues, Office of the Assistant Secretary for Health, Department of Health and Human Services.

ACTION: Notice of Meeting.

SUMMARY: The Presidential Commission for the Study of Bioethical Issues will conduct its thirteenth meeting on April 30, 2013. At this meeting, the Commission will discuss the ethical implications of incidental findings.

DATES: The meeting will take place Tuesday, April 30, 2013.

ADDRESSES: The Hamilton Crowne Plaza Hotel, 1001 14th St. NW., Washington, DC 20005. Telephone (202) 682–0111.

FOR FURTHER INFORMATION CONTACT: Hillary Wicai Viers, Communications Director, Presidential Commission for the Study of Bioethical Issues, 1425 New York Avenue NW, Suite C–100, Washington, DC 20005. Telephone: 202–233–3960. Email: *Hillary.Viers@bioethics.gov.* Additional information may be obtained at *www.bioethics.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act of 1972, Public Law 92–463, 5 U.S.C. app. 2, notice is hereby given of the thirteenth meeting of the Presidential Commission for the Study of Bioethical Issues (the Bioethics Commission). The meeting will be held from 9:00 a.m. to approximately 5:15 p.m. on Tuesday, April 30, 2013, in Washington, DC The meeting will be open to the public with attendance limited to space available. The meeting will also be webcast at *www.bioethics.gov.*

Under authority of Executive Order 13521, dated November 24, 2009, the President established the Bioethics Commission. The Bioethics Commission is an advisory panel of the nation's leaders in medicine, science, ethics, religion, law, and engineering. The Bioethics Commission advises the President on bioethical issues arising from advances in biomedicine and related areas of science and technology. The Bioethics Commission seeks to identify and promote policies and practices that ensure scientific research, health care delivery, and technological innovation are conducted in a socially and ethically responsible manner.

The main agenda item for the Bioethics Commission's thirteenth meeting is to discuss the ethical implications of incidental findings.

The draft meeting agenda and other information about the Bioethics Commission, including information about access to the webcast, will be available at *www.bioethics.gov.*

The Bioethics Commission welcomes input from anyone wishing to provide public comment on any issue before it. Respectful debate of opposing views and active participation by citizens in public exchange of ideas enhances overall public understanding of the issues at hand and conclusions reached by the Bioethics Commission. The Bioethics Commission is particularly interested in receiving comments and questions during the meeting that are responsive to specific sessions. Written comments will be accepted at the registration desk and comment forms will be provided to members of the public in order to write down questions and comments for the Bioethics Commission as they arise. To accommodate as many individuals as possible, the time for each question or comment may be limited. If the number of individuals wishing to pose a question or make a comment is greater than can reasonably be accommodated during the scheduled meeting, the Bioethics Commission may make a random selection.

Anyone planning to attend the meeting who needs special assistance, such as sign language interpretation or other reasonable accommodations, should notify Esther Yoo by telephone at (202) 233–3960, or email at *Esther.Yoo@bioethics.gov* in advance of the meeting. The Bioethics Commission will make every effort to accommodate persons who need special assistance.

Written comments will also be accepted in advance of the meeting and are especially welcome. Please address written comments by email to *info@bioethics.gov,* or by mail to the following address: Public Commentary, Presidential Commission for the Study of Bioethical Issues, 1425 New York Ave., NW., Suite C–100, Washington, DC 20005. Comments will be publicly available, including any personally identifiable or confidential business information that they contain. Trade secrets should not be submitted.

Dated: March 21, 2013.

Lisa M. Lee,

Executive Director, Presidential Commission for the Study of Bioethical Issues.

[FR Doc. 2013–08032 Filed 4–4–13; 8:45 am]

BILLING CODE 4154–06–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Federal Tax Offset, Administrative Offset, and Passport Denial.

OMB No.: 0970–0161.

Description: The Federal Tax Offset, Administrative Offset, and Passport Denial programs collect past-due child support by intercepting certain federal payments, including federal tax refunds, of parents who have been ordered to pay child support and who are behind in paying the debt. The program is a cooperative effort among the Department of the Treasury's Financial Management Service, the federal Office of Child Support Enforcement (OCSE), and state child support enforcement (CSE) agencies. The Passport Denial program reports noncustodial parents who owe child support above a threshold to the Department of State, which will then deny passports to these individuals. On an ongoing basis, CSE agencies submit to OCSE the names, Social Security numbers, and the amount(s) of past-due child support of people who are delinquent in making child support payments.

Respondents: State IV–D Agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Input Record	54	52	.3	842.4
Output Record	54	52	.46	1291.7
Payment File	54	52	.135	379.1
Certification Letter	54	1	.4	21.6
SSP FCE Processing screens—State Workers	146	337	.008	393.6
Total				2,928.4

Estimated Total Annual Burden Hours: 2928.4.

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov*.

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–7285, Email: *OIRA_SUBMISSION@OMB.EOP.GOV,* Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2013–07898 Filed 4–4–13; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[C.F.D.A. Number: 93.591]

Standing Funding Opportunity Announcement for Family Violence Prevention and Services/Grants to State Domestic Violence Coalitions

AGENCY: Family and Youth Services Bureau (FYSB), Administration on Children, Youth, and Families (ACYF), ACF.

ACTION: This notice was originally published as Funding Opportunity Number HHS–2013–ACF–ACYF–SDVC–0562 on March 5, 2013 at *http://www.acf.hhs.gov/grants/open/foa/view/HHS-2013-ACF-ACYF-SDVC-0562.*

SUMMARY: This notice for family violence prevention and services grants to Coalitions serves four purposes: To confirm a Federal commitment to reducing family violence, domestic violence, and dating violence; to provide for Coalitions to collaborate and coordinate with States, tribes, localities, cities, and the private sector to be involved in State and local planning towards an integrated service delivery approach that meets the needs of all victims, including those in underserved communities and racial and ethnic minorities; to provide training and technical assistance to domestic violence programs and providers of direct services; and to increase public awareness about and prevention of family violence, domestic violence, and dating violence, and increase the quality and availability of immediate shelter and supportive services for victims of family violence, domestic violence, and dating violence, and their dependents.

Statutory Authority: This announcement governs the proposed award of formula grants under the Family Violence Prevention and Services Act (FVPSA) to private, non-profit State Domestic Violence Coalitions (Coalitions). The purpose of these grants is to further the intervention and prevention of family violence, domestic violence, and dating violence (42 U.S.C. 10401, *et seq.*).

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

Description

Background

The FVPSA authorizes the Department of Health and Human Services (HHS) Secretary to award grants to statewide, private, non-governmental, 501(c)(3) non-profit Coalitions to conduct activities to promote domestic violence intervention and prevention.

Ensuring the Well-Being of Vulnerable Children and Families

The Administration on Children, Youth and Families (ACYF) is committed to facilitating healing and recovery and promoting the social and emotional well-being of children, youth,

and families who have experienced maltreatment, exposure to violence, and/or trauma. This funding opportunity announcement (FOA) and other discretionary spending this fiscal year are designed to ensure that effective interventions are in place to build skills and capacities that contribute to the healthy, positive, and productive functioning of families.

Children, youth, and families who have experienced maltreatment, exposure to violence, and/or trauma are impacted along several domains, each of which must be addressed in order to foster social and emotional well-being and promote healthy, positive functioning:

• *Understanding Experiences:* A fundamental aspect of the human experience is the development of a world view through which one's experiences are understood. Whether that perspective is generally positive or negative impacts how experiences are interpreted and integrated. For example, one is more likely to approach a challenge as a surmountable, temporary obstacle if his or her frame includes a sense that ''things will turn out alright.'' On the contrary, negative experiences can color how future experiences are understood. Ongoing exposure to family violence might lead children, youth, and adults to believe that relationships are generally hostile in nature and affect their ability to enter into and stay engaged in safe and healthy relationships. Interventions should seek to address how children, youth, and adults frame what has happened to them in the past and shape their beliefs about the future.

• *Developmental Tasks:* People grow physically and psychosocially along a fairly predictable course, encountering normal challenges and establishing competencies as they pass from one developmental stage to another. However, adverse events have a marked effect on the trajectory of normal social and emotional development, delaying the growth of certain capacities, and, in many cases, accelerating the maturation of others. Intervention strategies must be attuned to the developmental impact of negative experiences and address related strengths and deficits to ensure children, youth, and families develop along a healthy trajectory.

• *Coping Strategies:* The methods that children, youth, and families develop to manage challenges both large and small are learned in childhood, honed in adolescence, and practiced in adulthood. Those who have been presented with healthy stressors and opportunities to overcome them with appropriate encouragement and support are more likely to have an array of positive, productive coping strategies available to them as they go through life. For children, youth, and families who grew up in or currently live in unsafe, unpredictable environments, the coping strategies that may have been protective in the unsafe environments may not be appropriate for safer, more regulated situations. Interventions should help children, youth, and families transform maladaptive coping methods into healthier, more productive strategies.

• *Protective Factors:* A wealth of research has demonstrated that the presence of certain contextual factors (e.g., supportive relatives, involvement in after-school activities) and characteristics (e.g., self-esteem, relationship skills) can moderate the impacts of past and future negative experiences. These protective factors are fundamental to resilience; building them is integral to successful intervention with children, youth, and families.

The skills and capacities in these areas support children, youth, and families as challenges, risks, and opportunities arise. In particular, each domain impacts the capacity of children, youth, and families to establish and maintain positive relationships with caring adults and supportive peers. The necessity of these relationships to social and emotional well-being and lifelong success in school, community, and at home cannot be overstated and should be central to all interventions with vulnerable children, youth, and families.

An important component of promoting social and emotional well-being includes addressing the impact of trauma, which can have a profound effect on the overall functioning of children, youth, adults, and families. ACYF promotes a trauma-informed approach, which involves understanding and responding to the symptoms of chronic interpersonal trauma and traumatic stress across the domains outlined above, as well as the behavioral and mental health sequelae of trauma.

ACYF anticipates a continued focus on social and emotional well-being as a critical component of its overall mission to ensure positive outcomes for all children, youth, adults, and families.

Annual State Domestic Violence Coalition Grantee Meeting

Coalitions must send up to two representatives to the annual grantee meeting. Subsequent correspondence will advise Coalitions of the date, time, and location of their grantee meeting.

Role of State Coalitions

FVPSA directs Coalitions to work with family violence, domestic violence, and dating violence service programs and providers of direct services to encourage appropriate and comprehensive responses to family violence, domestic violence, and dating violence against adults or youth within the State involved, specifically including training and technical assistance and conducting State needs assessments (section 10411(d)(1)). Coalitions are required to coordinate and collaborate with the State FVPSA Administrators, community-based programs, and culturally specific organizations, including those serving racial and ethnic minorities, to plan and conduct State needs assessments and participate in State planning processes. These assessments are particularly important, not just, to identify and assess service gaps, but to include a diversity of stakeholders in the planning and decision-making process for needs assessments and to inform State planning. Coalitions must also participate in the planning and monitoring of the distribution of FVPSA subgrants and contracts and the administration of the grant programs and projects awarded by the States to eligible entities (section 10411(d)(2)). Coalitions thus play an important role in helping programs develop and continue practices consistent with FVPSA guidance, including the promotion of trauma-informed services that help facilitate the social and emotional well-being of both victims and their children. Coalitions must include activities to ensure that programs maintain confidentiality and provide widely accessible services consistent with best practices in the field and applicable Federal, State, tribal, and local requirements, as well as helping programs comply with the FVPSA data collection and outcome measurement requirements. Each of these issues is described below:

a. Client Confidentiality

Coalitions have an important role in helping programs develop and continue practices consistent with FVPSA guidance. Programs funded by FVPSA must establish and implement policies and protocols for maintaining the safety, privacy, and confidentiality of adult, youth, and child victims of family violence, domestic violence, and dating violence, and their families (section 10406(c)(5)). Because it is required that the confidentiality of individuals receiving FVPSA services be protected, Coalitions must include activities to

ensure that local programs maintain confidentiality consistent with best practices in the field and applicable Federal, State, tribal, and local requirements. It is also highly recommended that the Coalition coordinate and collaborate with the State involving activities to assist programs in maintaining confidentiality requirements pursuant to section 10406(c)(5).

The FVPSA nondisclosure of confidential and private information provisions also mean that domestic violence programs must maintain confidentiality of records pertaining to any individual provided domestic violence services. As a result, individual identifiers in client records may not be disclosed when providing statistical data on program activities and program services. In the annual grantee Performance Progress Report (SF–PPR), States, tribes, and their subgrantees must collect unduplicated data for each program rather than unduplicated data across programs or statewide. No client-level data should be shared with a third party, regardless of encryption, hashing or other data security measures, without a written, time-limited release as described in section 10406(c)(5)(B)(ii).

b. Coordinated and Accessible Services

It is essential that community service providers, including those serving or representing underserved communities, are involved in the design and improvements of intervention and prevention activities to ensure that services are welcoming and accessible. Coordination and collaboration among victim services providers; community-based, culturally specific, and faith-based services providers; housing and homeless services providers: and, Federal, State, tribal, and local public officials and agencies is needed to provide more responsive and effective services to victims of family violence, domestic violence, and dating violence, and their dependents. As coalitions undertake these activities, it is expected that the communities and populations noted above will be included in coalition boards, committees, and other activities to ensure they are part of the decision making to create and maintain fully coordinated and accessible services.

To promote a more effective response to family violence, domestic violence, and dating violence, HHS requires the designated Coalitions receiving funds under this grant announcement to collaborate with tribes and tribal organizations, FVPSA-funded State grantees, service providers, and community-based organizations, to address the needs of family violence, domestic violence, and dating violence victims, and their dependents, who are members of racial and ethnic minority populations and underserved populations (section 10411(d)(3)); examples of such underserved populations include, but are not limited to, the Lesbian, Gay, Bisexual, and Transgender (LGBT) communities; adolescents; male victims; human trafficking victims; and immigrants. Coalition training and technical assistance priorities should focus on building the capacity of domestic violence programs within the State to provide inclusive and culturally relevant services for the underserved populations identified in their planning. All populations identified in planning should also be a part of determining the training and technical assistance priorities to improve the capacity of programs to serve such populations. ACYF/FYSB also strongly encourages Coalitions to consider the needs of LGBT youth and adults and how their programming and, therefore, the training and technical assistance provided member programs, will be inclusive and non-stigmatizing for program participants from these communities.

To serve victims most in need and to comply with Federal law, services must be widely accessible. Services must not discriminate on the basis of age, disability, sex, race, color, national origin, or religion (section 10406(c)(2)). The HHS Office for Civil Rights provides guidance to grantees in complying with civil rights laws that prohibit discrimination on these bases. Please see *www.hhs.gov/ocr/civilrights/understanding/index.html.* HHS also provides guidance to recipients of Federal financial assistance on meeting the legal obligation to take reasonable steps to provide meaningful access to federally assisted programs by persons with limited English proficiency. Please see *www.hhs.gov/ocr/civilrights/resources/laws/revisedlep.html.* Additionally, HHS provides guidance regarding access to HHS-funded services for immigrant survivors of domestic violence. Please see *www.hhs.gov/ocr/civilrights/resources/specialtopics/origin/domesticviolencefactsheet.html*

Services must also be provided on a voluntary basis; receipt of emergency shelter or housing must not be conditioned on participation in supportive services (section 10408(d)(2)).

c. Trauma-Informed Programming

ACYF promotes a trauma-informed approach, which involves understanding and responding to the symptoms of chronic interpersonal trauma and traumatic stress across the lifespan. Coalitions are uniquely situated to provide support to domestic violence programs in order to ensure that trauma-informed interventions are at the core of working with victims and their children. As Coalitions plan their training and technical assistance priorities, they must include responses that help support trauma-informed services among their member programs to ensure positive outcomes for all service populations. Coalitions must also coordinate and collaborate with the Domestic Violence Resource Network (the FVPSA-funded National Resource, Special Issue Resource, and Culturally-Specific Resource Centers) to inform their knowledge and practices to promote trauma-informed interventions among their member programs.

II. Award Information

Subject to the availability of Federal appropriations and as authorized by the FVPSA (section 10403), HHS will make available in FY 2013, 2014, and 2015 grants to the designated, statewide, domestic violence Coalitions described in this announcement. Each year, one grant will be available for one Coalition in each of the 50 States, the Commonwealth of Puerto Rico, and the District of Columbia. One Coalition in each of the U.S. Territories (Guam, U.S. Virgin Islands, Northern Mariana Islands, and American Samoa) is also eligible for a grant award under this announcement.

Length of Project Periods

Coalitions may apply for one grant annually with an accompanying 12-month budget narrative and SF–424. The project period is 24 months under this FOA for each fiscal year. Coalitions must address their anticipated activities for a 2-year project period: (FY 2013) October 1, 2012–September 30, 2014; (FY 2014) October 1, 2013–September 30, 2015; (FY 2015) October 1, 2014–September 30, 2016. FVPSA will continue to disperse funds annually pursuant to annual applications and award processes.

Expenditure Period

The FVPSA funds may be used for expenditures on or after October 1 of each fiscal year for which they are granted and will be available for expenditure through September 30 of the following fiscal year; i.e., FY 2013 funds may be used for expenditures from October 1, 2012, through September 30, 2014; (FY 2014) October

1, 2013–September 30, 2015; (FY 2015) October 1, 2014–September 30, 2016.

III. Eligibility Information

In accordance with sections 10402(11) and 10411(c)(1), to be eligible for grants under this FOA an organization must be designated as a statewide, private, 501(c)(3) nonprofit, non-governmental domestic violence coalition as of the date of this announcement. A list of the designated State domestic violence coalitions is found in Appendix D. Designated coalitions must continue to meet the following criteria:

The membership of the Coalition includes a majority of the primary-purpose domestic violence service providers in the State (a Coalition may include representatives of Indian tribes and tribal organizations as defined in the Indian Self-Determination and Education Assistance Act). A primary-purpose domestic violence service provider is one that operates a project of demonstrated effectiveness, carried out by a nonprofit, nongovernmental, private entity or a tribe or tribal organization, that has as its project's primary purpose the operation of shelters for victims of domestic violence and their dependents; or provides counseling, advocacy, or self-help services to victims of domestic violence;

The board membership of the Coalition is representative of the primary-purpose domestic violence service providers in the State and may include representatives of the communities in which the services are being provided in the State; in order for statewide needs assessments and other organizational and State planning to be fully informed directly by stakeholders from diverse communities, it is expected that the Coalition board will reflect the cultural, racial, and ethnic populations that the Coalition serves throughout the State;

The purpose of the Coalition is to provide education, support, and technical assistance to the primary-purpose domestic violence service providers and providers of direct services in the State in order to establish and maintain shelter and supportive services for victims of domestic violence and their dependents;

The Coalition serves as an information clearinghouse, primary point of contact, and resource center on domestic violence for the State and supports the development of policies, protocols, and procedures to enhance domestic violence intervention and prevention in the State.

Additional Information on Eligibility

DUNS Number Requirement

Data Universal Numbering System (DUNS) Number is the nine-digit, or thirteen-digit (DUNS + 4), number established and assigned by Dun and Bradstreet, Inc. (D&B) to uniquely identify business entities.

All applicants and sub-recipients must have a DUNS number at the time of application in order to be considered for a grant or cooperative agreement. A DUNS number is required whether an applicant is submitting a paper application or using the Government-wide electronic portal, *www.Grants.gov.* A DUNS number is required for every application for a new award or renewal/continuation of an award, including applications or plans under formula, entitlement, and block grant programs. A DUNS number may be acquired at no cost online at *http://fedgov.dnb.com/webform.* To acquire a DUNS number by phone, contact the D&B Government Customer Response Center:

U.S. and U.S. Virgin Islands: 1–866–705–5711
Alaska and Puerto Rico: 1–800–234–3867 (Select Option 2, then Option 1)
Monday–Friday 7 a.m. to 8 p.m., CST

The process to request a DUNS Number by telephone will take between 5 and 10 minutes.

SAM Requirement (www.Sam.gov)

The System for Award Management (SAM) at *www.sam.gov* is a new system that consolidates the capabilities of a number of systems that support Federal procurement and award processes. Phase 1 of SAM includes the capabilities previously provided via Central Contractor Registration (CCR)/Federal Agency Registration (FedReg), Online Representations and Certifications Application (ORCA), and the Excluded Parties List System (EPLS).

SAM is the Federal registrant database and repository into which an entity must provide information required for the conduct of business as a recipient. The former CCR Web site is no longer be available. All information previously held in the Central Contractor Registration (CCR) system has been migrated to SAM.gov.

Applicants may register at *www.sam.gov* or by phone at 1–866–606–8220. Registration assistance is available through the ''Help'' tab at *www.sam.gov* or by phone at 1–866–606–8220.

Applicants are strongly encouraged to register at SAM well in advance of the application due date. Registration at SAM.gov must be updated annually.

Note: It can take 24 hours or more for updates to registrations at SAM.gov to take effect. An entity's registration will become active after 3–5 days. Therefore, check for active registration well before the application due date and deadline. An applicant can view their registration status by visiting *http://www.bpn.gov/CCRSearch/Search.aspx* and searching by their organization's DUNS number.

See the SAM Quick Guide for Grantees at *https://www.sam.gov/sam/transcript/SAM_Quick_Guide_Grants_Registrations-v1.6.pdf.*

HHS requires all entities that plan to apply for, and ultimately receive, Federal grant funds from any HHS Agency, or receive subawards directly from recipients of those grant funds to:

- Be registered in at Sam.gov prior to submitting an application or plan;
- Maintain an active registration at *www.sam.gov* with current information at all times during which it has an active award or an application or plan under consideration by an HHS agency; and
- Provide its active DUNS number in each application or plan it submits to an HHS agency.

ACF is prohibited from making an award to an applicant has not complied with these requirements. If, at the time an award is ready to be made, if the intended recipient has not complied with these requirements, ACF:

- May determine that the applicant is not qualified to receive an award; and
- May use that determination as a basis for making an award to another applicant.

Additionally, all first-tier subaward recipients (i.e., direct subrecipients) must have an active DUNS number at the time the subaward is made.

IV. Application Requirements

This section includes application requirements for FVPSA grants for Coalitions, as follows:

Content of Application Submission

The Coalition application must be signed by the Executive Director of the Coalition or the official designated as responsible for the administration of the grant. The application must contain the following information:

(1) A description of the process and anticipated outcomes (including timelines and specific activities that lead to desired outcomes) of utilizing these Federal funds to work with family violence, domestic violence, and dating violence service programs and providers of direct services to encourage appropriate and comprehensive responses to family violence, domestic violence, and dating violence against adults or youth within the State,

including providing training and technical assistance and conducting statewide needs assessments (section 10411(d)(1)); include in the statewide needs assessment description a statement of how the needs assessment is undertaken in coordination and collaboration with the State's Plan for FVPSA formula grant funding and how representatives of underserved communities and racial and ethnic minority populations are included in the planning and decision-making;

(2) A description of the process undertaken and procedures developed to participate in the planning and monitoring of the distribution of FVPSA State subgrants and subgrant funds (section 10411(d)(2)), as well as the administration of FVPSA State-funded grant programs and projects;

(3) A description of collaborations along with anticipated outcomes (including timelines and specific activities that lead to desired outcomes) with service providers and community-based organizations to address the needs of family violence, domestic violence, and dating violence victims, and their dependents, who are members of racial and ethnic minority populations and underserved populations (section 10411(d)(3)); also include a description of the training or technical assistance or other activities provided to direct service providers to ensure programs are welcoming and accessible; examples of such underserved populations include, but are not limited to, the Lesbian, Gay, Bisexual, and Transgender (LGBT) communities; adolescents; men; immigrants; and human trafficking victims.

(4) A description of collaborations and anticipated outcomes (including timelines and specific activities that lead to desired outcomes) for providing information to entities in such fields as housing, health care, mental health, social welfare, or business to support the development and implementation of effective policies, protocols, and programs that address the safety and support needs of adult and youth victims of family violence, domestic violence, or dating violence (section 10411(d)(4));

(5) A description of work and anticipated outcomes (including timelines and specific activities that lead to desired outcomes) to encourage appropriate responses to cases of family violence, domestic violence, or dating violence against adults or youth, including by working with judicial and law enforcement officers (Section 10411(d)(5)) unless the applicant coalition satisfies the exception described in paragraph (7) below;

(6) A description of activities and anticipated outcomes (including timelines and specific activities that lead to desired outcomes) associated with working with family law judges, criminal court judges, child protective service agencies, and children's advocates to develop appropriate responses to child custody and visitation issues in cases of child exposure to family violence, domestic violence, or dating violence, and in cases in which family violence, domestic violence, or dating violence is present and child abuse is present (Section 10411(d)(6)) unless the applicant coalition satisfies the exception described in paragraph (7) below.

(7) If the applicant coalition uses funds received under the Violence Against Women Act for State domestic violence coalitions for the purposes described in paragraphs (5) and (6) above and is coordinating those activities with the State's STOP (Services, Training, Officers, Prosecutors) formula grant activities that address those purposes, the applicant Coalition shall not be required to undertake additional activities. If applicable, the applicant Coalition must provide a statement of assurance that funds for the referenced purposes are received from the Office on Violence Against Women (OVW), U.S. Department of Justice, and that the activities are coordinated with the State's STOP formula grant activities, (Section 10411(e)(1) and (2)); as part of the assurance the applicant coalition must also describe its activities in those OVW-funded areas including those in collaboration with the State STOP grant activities;

(8) A description of work and anticipated outcomes (including timelines and specific activities that lead to desired outcomes) to provide information to the public about prevention of family violence, domestic violence, and dating violence, including information targeted to underserved communities; examples of such communities include, but are not limited to, LGBT communities, adolescents, male victims, immigrants, and human trafficking victims (section 10411(d)(7));

(9) A description of collaborations (including timelines, specific activities, and outcomes) with Indian tribes and tribal organizations (and corresponding Native Hawaiian groups and communities) to address the needs of Native American (including Alaska Native) and Native Hawaiian victims of family violence, domestic violence, or dating violence, as applicable in the State (section 10411(d)(8)). Note: Tribes have special sovereign status and, as such, collaborations with them must include the opportunity for Coalition membership provided they meet general membership eligibility requirements that are not impediments to their special sovereign status; Coalitions are urged to seek technical assistance, if needed, from the National Indigenous Women's Resource Center for assistance in meeting this program requirement. Coalitions may include a description of the technical assistance received as well as plans to implement the technical assistance to support their applications;

(10) A description of work and anticipated outcomes (including timelines and activities) associated with other activities to support the development of policies, protocols, and procedures to enhance domestic violence intervention and prevention in the State (section 10402(11)); also include a description of the participation of underserved and culturally specific populations in the planning and decision-making regarding any additional work identified in this requirement;

(11) To support ACYF priorities as described in Section 1. c. Trauma-Informed Programming, a description of work planned (including timelines and activities) to gauge the activities of domestic violence programs offering trauma-informed services that address lifetime exposure to violence, including trauma-focused intervention strategies. Such work shall also include a capacity assessment of all member programs to identify those needing additional training, technical assistance and support related to trauma-informed service provision;

(12) A description of activities to describe the applicant Coalition's role as an information clearinghouse, primary point of contact, and resource center on domestic violence for the State; include the participation of underserved and culturally specific populations in identifying the kinds of resource information and other data needed to meet the unique needs of such populations.

(13) The following documentation that certifies the status of the Coalition must be included in the grant application:

(a) A copy of a currently valid 501(c)(3) certification letter from the IRS stating private, non-profit status; or a copy of the applicant's listing in the IRS' most recent list of tax-exempt organizations described in section 501(c)(3) of the IRS code;

(b) To demonstrate compliance with section 10402(11):

(i) A current list of the organizations operating programs for victims of domestic violence in the State; a list of the primary-purpose domestic violence services providers in the State; and, the applicant Coalition's current membership list by organization, including a notation of culturally specific organizations represented in the membership structure (see *Section III. Eligibility*);

(ii) A list of the applicant Coalition's current Board of Directors, with each individual's organizational affiliation and the Chairperson identified (see *Section III. Eligibility*);

(14) A list of any Coalition or contractual positions to be supported by funds from this grant;

(15) A budget narrative that clearly describes the planned expenditure of funds under this grant including a provision that sets aside funds for travel expenses for up to two staff to the Annual State Domestic Violence Coalition grantee meeting;

(16) A description of the applicant's organizational policies and procedures to maintain victim confidentiality, as well as activities, training, and/or technical assistance to support member programs' confidentiality practices to support victim safety; and, a description of the activities undertaken with the FVPSA state administrator to ensure victim confidentiality in domestic violence programs.

Forms, Assurances, and Certifications

Applicants seeking financial assistance under this announcement must submit the listed Standard Forms (SFs) and certifications. All required Standard Forms and certifications are available at the *Grants.gov Forms Repository* unless specified otherwise.

Additional Assurance and Policy

Each application must provide a signed copy of the additional assurance and policy in Appendices A and E, respectively.

Forms/certifications	Description	Where Found
Certification Regarding Lobbying	Required of all applicants at the time of their application. If not available with the application, it must be submitted prior to the award of the grant.	Available at *www.acf.hhs.gov/grants/grants_resources.html.*
SF–LLL—Disclosure of Lobbying Activities	If any funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this commitment providing for the United States to insure or guarantee a loan, the applicant shall complete and submit the SF–LLL, ''Disclosure Form to Report Lobbying,'' in accordance with its instructions. Applicants must furnish an executed copy of the Certification Regarding Lobbying prior to award.	''Disclosure Form to Report Lobbying'' is available at *www.acf.hhs.gov/grants/grants_resources.html.*
Survey on Ensuring Equal Opportunity for Applicants.	Non-profit private organizations (not including private universities) are encouraged to submit the survey with their applications. Submission of the survey is voluntary. Applicants applying electronically may submit the survey along with the application as part of an appendix or as a separate document. Hard copy submissions should include the survey in a separate envelope.	Available at *www.acf.hhs.gov/grants/grants_resources.html.*
The needs of lesbian, gay, bisexual, transgender, and questioning youth are taken into consideration in applicants program design.	See Appendix E for submission requirements	See Appendix E for the complete policy description.

Paperwork Reduction Disclaimer

The Project Description information collection is approved under OMB control number 0970–0280, which expires November 30, 2014.

As required by the Paperwork Reduction Act, 44 U.S.C. 3501–3520, the public reporting burden for the project description is estimated to average 10 hours per response, including the time for reviewing instructions, gathering and maintaining the data needed, and reviewing the collection of information. The Project Description information collection is approved under OMB control number 0970–0280, which expires November 30, 2014. 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.

Funding Restrictions

The Consolidated Appropriations Act, 2012 (Pub. L. 112–74), enacted December 23, 2011, limits the salary amount that may be awarded and charged to ACF mandatory and discretionary grants. Award funds issued under this announcement may not be used to pay the salary, or any percentage of salary, to an individual at a rate in excess of Executive Level II. The Executive Level II salary of the Federal Executive Pay scale is $179,700 (*/www.opm.gov/oca/12tables/html/ex.asp*). This amount reflects an individual's base salary exclusive of fringe benefits and any income that an individual may be permitted to earn outside of the duties to the applicant organization. This salary limitation also applies to subawards/subcontracts under an ACF mandatory and discretionary grant.

Costs of organized fund raising, including financial campaigns, endowment drives, solicitation of gifts and bequests, and similar expenses incurred solely to raise capital or obtain

contributions, are considered unallowable costs under grants awarded under this announcement.

Construction is not an allowable activity or expenditure under this grant award.

Application Submission

Applications should be sent or delivered to:

Administration for Children and Families,
Administration on Children, Youth and Families,
Family and Youth Services Bureau,
Division of Family Violence Prevention and Services,
ATTN: Kenneth E. Noyes, J.D., 1250 Maryland Avenue SW., Suite 8212, Washington, DC 20024

V. Award Administration Information

Administrative and National Policy Requirements

Awards issued under this announcement are subject to the uniform administrative requirements and cost principles of 45 CFR Part 74 (Awards and Subawards to Institutions of Higher Education, Hospitals, Other Nonprofit Organizations, and Commercial Organizations) or 45 CFR Part 92 (Grants and Cooperative Agreements to State, Local, and Tribal Governments). The Code of Federal Regulations (CFR) is available at *www.gpo.gov.*

An application funded with the release of Federal funds through a grant award, does not constitute, or imply, compliance with Federal regulations. Funded organizations are responsible for ensuring that their activities comply with all applicable Federal regulations.

Equal Treatment for Faith-Based Organizations

Grantees are also subject to the requirements of 45 CFR 87.1(c), Equal Treatment for Faith-Based Organizations, which says, ''Organizations that receive direct financial assistance from the [Health and Human Services] Department under any Department program may not engage in inherently religious activities such as worship, religious instruction, or proselytization, as part of the programs or services funded with direct financial assistance from the Department.'' Therefore, organizations must take steps to completely separate the presentation of any program with religious content from the presentation of the Federally funded program by time or location in such a way that it is clear that the two programs are separate and distinct. If separating the two programs by time but presenting them in the same location, one program must completely end before the other program begins.

A faith-based organization receiving HHS funds retains its independence from Federal, State, and local governments, and may continue to carry out its mission, including the definition, practice, and expression of its religious beliefs. For example, a faith-based organization may use space in its facilities to provide secular programs or services funded with Federal funds without removing religious art, icons, scriptures, or other religious symbols. In addition, a faith-based organization that receives Federal funds retains its authority over its internal governance, and it may retain religious terms in its organization's name, select its board members on a religious basis, and include religious references in its organization's mission statements and other governing documents in accordance with all program requirements, statutes, and other applicable requirements governing the conduct of HHS-funded activities.

Regulations pertaining to the Equal Treatment for Faith-Based Organizations, which includes the prohibition against Federal funding of inherently religious activities, ''Understanding the Regulations Related to the Faith-Based and Neighborhood Partnerships Initiative'' are available at *www.hhs.gov/partnerships/about/regulations/.* Additional information, resources, and tools for faith-based organizations is available through The Center for Faith-based and Neighborhood Partnerships Web site at *www.hhs.gov/partnerships/index.html* and at the *Administration for Children & Families: Toolkit for Faith-based and Community Organizations.*

Requirements for Drug-Free Workplace

The Drug-Free Workplace Act of 1988 (41 U.S.C. 8102 *et seq.*) requires that all organizations receiving grants from any Federal agency agree to maintain a drug-free workplace. By signing the application, the Authorizing Official agrees that the grantee will provide a drug-free workplace and will comply with the requirement to notify ACF if an employee is convicted of violating a criminal drug statute. Failure to comply with these requirements may be cause for debarment. Government-wide requirements for Drug-Free Workplace for Financial Assistance are found in 2 CFR part 182; HHS implementing regulations are set forth in 2 CFR 382.400. All recipients of ACF grant funds must comply with the requirements in Subpart B—Requirements for Recipients Other Than Individuals, 2 CFR 382.225. The rule is available at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr;sid=18b5801410be6af416dc258873ffb7ec;rgn=div2;view=text;node=20091112%3A1.1;idno=49;cc=ecfr.*

Debarment and Suspension

HHS regulations published in 2 CFR part 376 implement the government-wide debarment and suspension system guidance (2 CFR part 180) for HHS' non-procurement programs and activities. ''Non-procurement transactions'' include, among other things, grants, cooperative agreements, scholarships, fellowships, and loans. ACF implements the HHS Debarment and Suspension regulations as a term and condition of award. Grantees may decide the method and frequency by which this determination is made and may check the Excluded Parties List System (EPLS) located at *www.sam.gov/,* although checking the EPLS is not required. More information is available at *www.acf.hhs.gov/grants/grants_resources.html.*

Pro-Children Act

The Pro-Children Act of 2001, 20 U.S.C. 7181 through 7184, imposes restrictions on smoking in facilities where federally funded children's services are provided. HHS grants are subject to these requirements only if they meet the Act's specified coverage. The Act specifies that smoking is prohibited in any indoor facility (owned, leased, or contracted for) used for the routine or regular provision of kindergarten, elementary, or secondary education or library services to children under the age of 18. In addition, smoking is prohibited in any indoor facility or portion of a facility (owned, leased, or contracted for) used for the routine or regular provision of federally funded health care, day care, or early childhood development, including Head Start services, to children under the age of 18. The statutory prohibition also applies if such facilities are constructed, operated, or maintained with Federal funds. The statute does not apply to children's services provided in private residences, facilities funded solely by Medicare or Medicaid funds, portions of facilities used for inpatient drug or alcohol treatment, or facilities where WIC coupons are redeemed. Failure to comply with the provisions of the law may result in the imposition of a civil monetary penalty of up to $1,000 per violation and/or the imposition of an administrative compliance order on the responsible entity.

VI. Reporting Requirements

Performance Progress Reports (PPR)

The Coalition grantee must submit an annual report of activities describing the coordination, training and technical assistance, needs assessment, and comprehensive planning activities carried out pursuant to its activities as delineated in its response to this announcement. Additionally, the Coalition must report on the public information and education services provided; the activities conducted in conjunction with judicial and law enforcement agencies notwithstanding that such activities may be conducted pursuant to a coalition grant from the Office on Violence Against Women, U.S. Department of Justice, in coordination with the applicable State's STOP formula grant activities as described in *Section IV. Application Requirements,* number 7; the actions conducted in conjunction with other agencies, such as the State child welfare agency, notwithstanding that such activities may be conducted pursuant to a coalition grant from the Office on Violence Against Women, U.S. Department of Justice, in coordination with the applicable State's STOP formula grant activities as described in *Section IV. Application Requirements,* number 7; activities conducted in conjunction with community-based, culturally specific service providers or organizations serving or representing underserved communities; and any other activities undertaken under this grant award. All activities should include both a narrative explanation and statistical data to support the activities reported. The annual report also must provide an assessment of the effectiveness of grant-supported activities. Further guidance regarding assessment requirements will be provided in 2013. Any evaluation activities conducted with FVPSA funds must also be reported including submission of final evaluation reports, if any. This form is found at *www.acf.hhs.gov/programs/fysb/resource/ppr-fvpsa-coalitions.*

The annual report must be submitted using the Standard Form—Performance Progress Report (SF–PPR) applicable to this program.

The annual report is due 90 days after the end of the fiscal year in which the grant is awarded; i.e., December 29. Annual reports should be sent to:

Family Violence Prevention and Services Program,
Family and Youth Services Bureau,
Administration on Children, Youth and Families,
Administration for Children and Families,
Attention: Kenneth E. Noyes, J.D., 1250 Maryland Avenue SW., Room 8212, Washington, DC 20024.

Please note that HHS may suspend funding for an approved application if any applicant fails to submit an annual performance report or if the funds are expended for purposes other than those set forth under this announcement.

Federal Financial Reports (FFR)

Grantees must submit annual Financial Status Reports. The SF–425 is due December 29, 2013. The final SF–425 is due December 29, 2014. The SF–425 can be found at *www.whitehouse.gov/omb/grants/grants_forms.html.* Grantees have the option to submit their reports online through the Online Data Collection (OLDC) system at *https://extranet.acf.hhs.gov/ssi.*

Failure to submit reports on time may be a basis for withholding grant funds, suspension, or termination of the grant. In addition, all funds reported after the obligation period will be recouped. Completed reports should be sent to:

Matthew McMahon, Program Specialist,
Office of Grants Management,
Office of Administration,
Administration for Children and Families,
370 L'Enfant Promenade, SW., 6th Floor, Washington, DC 20447.

Fillable versions of the SF–425 form in Adobe PDF and MS-Excel formats, along with instructions, are available at *www.whitehouse.gov/omb/grants_forms*, *www.forms.gov,* and on the *ACF Funding Opportunity Web site Forms* page.

Also note that a separate, quarterly financial report is required by the Division of Payment Management using the SF–425. The Division of Payment Management's online Payment Management System (PMS) is required for filing quarterly reports and is found at the following address: *www.dpm.psc.gov.* For further assistance, please call the HHS helpline at 877–614–5533.

VII. FFATA Subaward and Executive Compensation

Awards issued as a result of this funding opportunity may be subject to the Transparency Act subaward and executive compensation reporting requirements of 2 CFR Part 170. See ACF's *Award Term for Federal Financial Accountability and Transparency Act (FFATA) Subaward and Executive Compensation Reporting Requirement* implementing this requirement and additional award applicability information.

ACF has implemented the use of the SF–428 *Tangible Property Report* and the SF–429 *Real Property Status Report* for all grantees. Both standard forms are available at *www.whitehouse.gov/omb/grants_forms/.*

VIII. Agency Contact

Program Office Contact

For Further Information Contact: Ken Noyes at (202) 205–7891 or email at: *kenneth.noyes@acf.hhs.govmailto:.*

Appendices

Required Assurance, Certification and Policy:

A. Programmatic Assurances
B. Assurance of Compliance with Grant Requirements
C. Certification Regarding Lobbying
D. Designated State Domestic Violence Coalitions
E. LGBTQ Accessibility Policy

Dates: The application due date is April 4, 2013.

For Further Information Contact: Kenneth E. Noyes, J.D. at (202) 205–7891 or email at: *kenneth.noyes@acf.hhs.gov.*

Bryan Samuels

Commissioner, Administration on Children, Youth and Families.

Appendix A—Programmatic Assurances

The grantee certifies that it will comply with the following assurances under the Family Violence Prevention and Services Act, 42 U.S.C. 10401, *et seq.*

(1) The applicant Coalition will use grant funds awarded under the Family Violence Prevention and Services Act (FVPSA) for administration and operations to further the purposes of family violence, domestic violence, and dating violence (as defined in section 10402(2), (3), and (4)).

(2) The applicant Coalition will use grant funds to work with local family violence, domestic violence, and dating violence service programs and providers of direct services to encourage appropriate and comprehensive responses to family violence, domestic violence, and dating violence against adults or youth within the State (section 10411(d)(1)).

(3) The applicant Coalition will undertake and develop procedures to participate in the planning and monitoring of the distribution of FVPSA State subgrants and subgrant funds (section 10411(d)(2), as well as the administration of FVPSA State-funded grant programs and projects.

(4) The applicant Coalition will use grant funds to work in collaboration with service providers and community-based organizations to address the needs of family violence, domestic violence, and dating violence victims, and their dependents, who are members of racial and ethnic minority

populations and underserved populations (section 10411(d)(3)).

(5) The applicant Coalition will use grant funds to collaborate with and provide information to entities in such fields as housing, health care, mental health, social welfare, or business to support the development and implementation of effective policies, protocols, and programs that address the safety and support needs of adult and youth victims of family violence, domestic violence, or dating violence (section 10411(d)(4)).

(6) The applicant Coalition will use grant funds to encourage appropriate responses to cases of family violence, domestic violence, or dating violence against adults or youth, including working with judicial and law enforcement agencies (section 10411(d)(5)). However, the applicant Coalition receiving funds under the FVPSA is not required to use funds received under the FPVSA if the Coalition provides an annual assurance to the Division of Family Violence Prevention that the Coalition is: (1) Using funds received under the Violence Against Women Act for State Domestic Violence Coalitions for activities, collaboration, and coordination with judicial and law enforcement officers (section 2001(c)(1)) of the Omnibus Crime Control and Safe Streets Act of 1968, 42 U.S.C. 3796gg(c)(1); and, (2) coordinating the activities carried out by the Coalition with the State's STOP (Services, Training, Officers, Prosecutors) activities pursuant to the Violence Against Women Act (part T of title I of the Omnibus Crime Control and Safe Streets Act of 1968, 42 U.S.C. 3796gg *et seq.*) that addresses those purposes (section 10411(e)).

(7) The applicant Coalition will use grant funds to work with family law judges, criminal court judges, child protective service agencies, and children's advocates to develop appropriate responses to child custody and visitation issues in cases of child exposure to family violence, domestic violence, or dating violence in cases in which—(1) family violence, domestic violence, or dating violence is present; and, (2) child abuse is present (section 10411(d)(6)). However, the applicant Coalition receiving funds under the FVPSA is not required to use funds received under the FPVSA if the Coalition provides an annual assurance to the Division of Family Violence Prevention that the coalition is: (1) Using funds received under the Violence Against Women Act for State Domestic Violence Coalitions to address activities, training, and collaborations with family and court judges, child welfare agencies, and children's advocates, as well as responding to child custody and visitation issues when family violence, domestic violence, or dating violence are present and child abuse is present (section 2001(c)(1)) of the Omnibus Crime Control and Safe Streets Act of 1968, (42 U.S.C. 3796gg(c)(1)); and, (2) coordinating the activities carried out by the coalition with the State's STOP activities under part T of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796gg *et seq.*) that addresses those purposes (section 10411(e)).

(8) The applicant Coalition will use grant funds to provide information to the public about prevention of family violence, domestic violence, and dating violence, including information targeted to underserved populations (section 10411(d)(7)).

(9) The applicant Coalition will use grant funds to collaborate with Indian tribes and tribal organizations (and corresponding Native Hawaiian groups or communities) to address the needs of Indian (including Alaska Native) and Native Hawaiian victims of family violence, domestic violence, or dating violence, as applicable in the State (section 10411(d)(8)).

(10) The applicant Coalition will prohibit discrimination on the basis of age, handicap, sex, race, color, national origin or religion, as described in section 10406(c)(2).

(11) The applicant Coalition has established policies, procedures, and protocols to ensure compliance with the provisions of section 10406(c)(5) regarding non-disclosure of confidential or private information.

(12) Pursuant to section 10406(c)(5) the applicant will comply with requirements imposed by that section, which include, but are not limited to: (1) The grantee will not disclose any personally identifying information collected in connection with services requested (including services utilized or denied), through the grantee's funded activities, or reveal personally identifying information without informed, written, reasonably time-limited consent by the person about whom information is sought, whether for the FVPSA-funded activities or any other Federal or State program and in accordance with Section 10406(c)(5)(B)(ii); (2) the grantee will not release information compelled by statutory or court order unless adhering to the requirements of section 10406(c)(5)(C); (3) the grantee may share non-personally identifying information in the aggregate for the purposes enunciated in section 10406(c)(5)(D)(i) as well as for other purposes found in section 10406(c)(5)(D)(ii) and (iii).

(13) The applicant Coalition will not use grant funds, directly or indirectly, to influence the issuance, amendment, or revocation of any Executive Order or similar legal document by any Federal, State, or local agency, or to undertake to influence the passage or defeat of any legislation by the Congress, or any State or local legislative body, or State proposals by initiative petition, except where representatives of the Coalition are testifying or making other appropriate communications when formally requested to do so by a legislative body, a committee, or a member of such organization, or in connection with legislation or appropriations directly affecting the activities of the Coalition or any member of the Coalition (Section 10411(f)).

Name and Signature

Title

Organization

Appendix B—Assurance of Compliance With Grant Requirements

The undersigned certifies that:

The applicant Coalition will not use grant funds, directly or indirectly, to influence the issuance, amendment, or revocation of any Executive Order or similar legal document by any Federal, State, or local agency, or to undertake to influence the passage or defeat of any legislation by Congress, or any State or local legislative body, or State proposals by initiative petition, except where representatives of the Coalition are testifying or making other appropriate communications, either when formally requested to do so by a legislative body, a committee, or a member of such organization, or in connection with legislation or appropriations directly affecting the activities of the Coalition (section 10411(f)).

The applicant Coalition will prohibit discrimination on the basis of age, disability, sex, race, color, national origin, or religion, as described in section 10406(c)(2).

Signature

Title

Organization

Appendix C—Certification Regarding Lobbying

Certification for Contracts, Grants, Loans, and Cooperative Agreements

The undersigned certifies, to the best of his or her knowledge and belief, that:

No Federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of an agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.

If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the undersigned shall complete and submit Standard Form-LLL, ''Disclosure Form to Report Lobbying,'' in accordance with its instructions.

The undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly. This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by

section 1352, title 31, U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

Statement for Loan Guarantees and Loan Insurance

The undersigned states, to the best of his or her knowledge and belief, that:

If any funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this commitment providing for the United States to insure or guarantee a loan, the undersigned shall complete and submit Standard Form-LLL, ''Disclosure Form to Report Lobbying,'' in accordance with its instructions. Submission of this statement is a prerequisite for making or entering into this transaction imposed by section 1352, title 31, U.S. Code. Any person who fails to file the required statement shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

Signature

Title

Organization

Appendix D

State Domestic Violence Coalitions as Designated by the U.S. Department of Health and Human Services, Administration for Children and Families, Administration on Children, Youth and Families as of December 2011

Coalition name	City	State
Alabama Coalition Against Domestic Violence	Montgomery	AL
Alaska Network on Domestic Violence and Sexual Assault	Juneau	AK
American Samoa Alliance Against Domestic and Sexual Violence	Pago Pago	AS
Arizona Coalition Against Domestic Violence	Phoenix	AZ
Arkansas Coalition Against Domestic Violence	Little Rock	AR
California Partnership to End Domestic Violence	Sacramento	CA
Colorado Coalition Against Domestic Violence	Denver	CO
Connecticut Coalition Against Domestic Violence	E. Hartford	CT
Delaware Coalition Against Domestic Violence	Wilmington	DE
District of Columbia Coalition Against Domestic Violence	Washington	DC
Florida Coalition Against Domestic Violence	Tallahassee	FL
Georgia Coalition Against Domestic Violence	Decatur	GA
Guam Coalition Against Sexual Assault and Family Violence	Hagatna	GU
Hawaii State Coalition Against Domestic Violence	Honolulu	HI
Idaho Coalition Against Sexual & Domestic Violence	Boise	ID
Illinois Coalition Against Domestic Violence	Springfield	IL
Indiana Coalition Against Domestic Violence	Indianapolis	IN
Iowa Coalition Against Domestic Violence	Des Moines	IA
Kansas Coalition Against Sexual & Domestic Violence	Topeka	KS
Kentucky Domestic Violence Association	Frankfort	KY
Louisiana Coalition Against Domestic Violence	Baton Rouge	LA
Maine Coalition to End Domestic Violence	Augusta	ME
Maryland Network Against Domestic Violence	Bowie	MD
Jane Doe, Inc.—Massachusetts Coalition Against Sexual Assault and Domestic Violence	Boston	MA
Michigan Coalition Against Domestic & Sexual Violence	Okemos	MI
Minnesota Coalition for Battered Women	St. Paul	MN
Mississippi Coalition Against Domestic Violence	Jackson	MS
Missouri Coalition Against Domestic & Sexual Violence	Jefferson City	MO
Montana Coalition Against Domestic & Sexual Violence	Helena	MT
Nebraska Domestic Violence & Sexual Assault Coalition	Lincoln	NE
Nevada Network Against Domestic Violence	Reno	NV
New Hampshire Coalition Against Domestic & Sexual Violence	Concord	NH
New Jersey Coalition for Battered Women	Trenton	NJ
New Mexico Coalition Against Domestic Violence	Albuquerque	NM
New York State Coalition Against Domestic Violence	Albany	NY
North Carolina Coalition Against Domestic Violence	Durham	NC
Northern Marianas Coalition Against Sexual and Domestic Violence	Saipan	MP
North Dakota Council on Abused Women's Services	Bismarck	ND
Ohio Domestic Violence Network	Columbus	OH
Oklahoma Coalition Against Domestic Violence & Sexual Assault	Oklahoma City	OK
Oregon Coalition Against Domestic Violence & Sexual Assault	Portland	OR
Pennsylvania Coalition Against Domestic Violence	Harrisburg	PA
Coordinadora Paz para la Mujer, Inc. (Puerto Rico Coalition Against Domestic Violence)	San Juan	PR
Rhode Island Coalition on Domestic Violence	Warwick	RI
South Carolina Coalition Against Domestic Violence & Sexual Assault	Columbia	SC
South Dakota Coalition Against Domestic Violence & Sexual Assault	Pierre	SD
Tennessee Coalition Against Domestic & Sexual Violence	Nashville	TN
Texas Council on Family Violence	Austin	TX
Utah Domestic Violence Council	Salt Lake City	UT
Vermont Network Against Domestic & Sexual Violence	Montpelier	VT
Virginia Sexual & Domestic Violence Action Alliance	Richmond	VA
Virgin Islands Domestic Violence and Sexual Assault Council	Kingshill	VI
Washington State Coalition Against Domestic Violence	Seattle	WA
West Virginia Coalition Against Domestic Violence	Elkview	WV
Wisconsin Coalition Against Domestic Violence	Madison	WI
Wyoming Coalition Against Domestic Violence & Sexual Assault	Laramie	WY

Appendix E—LGBTQ Accessibility Policy

As the Authorized Organizational Representative (AOR) signing this application on behalf of [*Insert full, formal name of applicant organization*]

I hereby attest and certify that:

The needs of lesbian, gay, bisexual, transgender, and questioning people are taken into consideration in applicant's programming. Applicant has considered how its programming will be inclusive of and non-stigmatizing toward such individuals. If not already in place, awardee must establish and publicize policies prohibiting harassment based on race, sexual orientation, gender, gender identity (or expression), religion, and national origin. The submission of an application for this funding opportunity constitutes an assurance that applicant has or will put such policies in place within 12 months of the award. Awardees should ensure that all staff members are trained to prevent and respond to harassment or bullying in all forms during the award period. Within 12 months of the award awardee must be prepared to monitor claims, address them seriously, and document their corrective action(s) so all programming beneficiaries are assured that the applicant organization and its programming is safe, inclusive, and non-stigmatizing by design and in operation.

Insert Date of Signature:

Print Name and Title of the AOR:

Signature of AOR:

[FR Doc. 2013–08027 Filed 04/04/2013 at 8:45 a.m.]

[FR Doc. 2013–08027 Filed 4–4–13; 8:45 am]

BILLING CODE 4184–32–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Tribal Consultation Meeting

AGENCY: Administration for Children and Families' Office of Head Start (OHS), HHS.

ACTION: Notice of meeting.

SUMMARY: Pursuant to the Improving Head Start for School Readiness Act of 2007, Public Law 110–134, notice is hereby given of two 1-day Tribal Consultation Sessions to be held between the Department of Health and Human Services, Administration for Children and Families, Office of Head Start leadership and the leadership of Tribal Governments operating Head Start (including Early Head Start) programs. The purpose of these Consultation Sessions is to discuss ways to better meet the needs of American Indian and Alaska Native children and their families, taking into consideration funding allocations, distribution formulas, and other issues affecting the delivery of Head Start services in their geographic locations [42 U.S.C. 9835, 640(l)(4)].

DATES: May 9, 2013, and July 26, 2013.

ADDRESSES: 2013 Office of Head Start Tribal Consultation Sessions will be held at the following locations:

Thursday, May 9, 2013—Green Bay, Wisconsin—Radisson Hotel & Conference Center, 2040 Airport Drive, Green Bay, WI 54313; and

Friday, July 26, 2013—Tulsa, Oklahoma—Renaissance Tulsa Hotel & Convention Center, 6808 S. 107th East Avenue, Tulsa, OK 74133

FOR FURTHER INFORMATION CONTACT: Robert Bialas, Regional Program Manager, Region XI, Office of Head Start, email *Robert.Bialas@acf.hhs.gov* or phone (202) 205–9497. Additional information and online meeting registration is available at *http://eclkc.ohs.acf.hhs.gov/hslc/eclkc_main_calendar/tc-2013.*

SUPPLEMENTARY INFORMATION: The Department of Health and Human Services (HHS) announces Office of Head Start (OHS) Tribal Consultations for leaders of Tribal Governments operating Head Start and Early Head Start programs. As much as possible, the OHS Tribal Consultations are being scheduled in conjunction with other tribal events. The Consultation in Tulsa will be held in conjunction with the Oklahoma Indian Head Start Directors Association (OIHSDA) Conference. Such scheduling is an effort to minimize the burden of travel for tribal participants. Tribal Consultation dates and locations for other parts of the country, including Alaska, will be announced at a later date.

The agenda for the scheduled OHS Tribal Consultations will be organized around the statutory purposes of Head Start Tribal Consultations related to meeting the needs of American Indian/Alaska Native children and families, taking into consideration funding allocations, distribution formulas, and other issues affecting the delivery of Head Start services in their geographic locations. In addition, OHS will share actions taken and in progress to address the issues and concerns raised in 2012 OHS Tribal Consultations.

Tribal leaders and designated representatives interested in submitting written testimony or proposing specific agenda topics for these Consultation Sessions should contact Robert Bialas at *Robert.Bialas@acf.hhs.gov.* Proposals must be submitted at least 3 days in advance of each session and should include a brief description of the topic area, along with the name and contact information of the suggested presenter.

The Consultation Session will be conducted with elected or appointed leaders of Tribal Governments and their designated representatives [42 U.S.C. 9835, 640(l)(4)(A)]. Designees must have a letter from the Tribal Government authorizing them to represent the tribe. The letter should be submitted at least 3 days in advance of the Consultation Session to Robert Bialas via fax at 866–396–8843. Other representatives of tribal organizations and Native nonprofit organizations are welcome to attend as observers.

A detailed report of the Consultation Session will be prepared and made available within 45 days of the Consultation Session to all Tribal Governments receiving funds for Head Start and Early Head Start programs. Tribes wishing to submit written testimony for the report should send testimony to Robert Bialas at *Robert.Bialas@acf.hhs.gov* either prior to the Consultation Session or within 30 days after the meeting.

Oral testimony and comments from the Consultation Session will be summarized in each report without attribution, along with topics of concern and recommendations. Hotel and logistical information for the Consultation Session has been sent to tribal leaders via email and posted on the Early Childhood Learning and Knowledge Center Web site at *http://eclkc.ohs.acf.hhs.gov/hslc/eclkc_main_calendar/tc-2013.*

Dated: March 26, 2013.

Yvette Sanchez Fuentes,

Director, Office of Head Start.

[FR Doc. 2013–08029 Filed 4–4–13; 8:45 am]

BILLING CODE 4184–40–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0375]

Agency Information Collection Activities; Proposed Collection; Comment Request; Agreement for Shipment of Devices for Sterilization

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the

PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements relating to shipment of nonsterile devices that are to be sterilized elsewhere or are shipped to other establishments for further processing, labeling, or repacking.

DATES: Submit either electronic or written comments on the collection of information by June 4, 2013.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *daniel.gittleson@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Agreement for Shipment of Devices for Sterilization—21 CFR 801.150(e) (OMB Control Number 0910–0131)—Extension

Under sections 501(c) and 502(a) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 351(c) and 352(a)), nonsterile devices that are labeled as sterile but are in interstate transit to a facility to be sterilized are adulterated and misbranded. FDA regulations in § 801.150(e) (21 CFR 801.150(e)) establish a control mechanism by which firms may manufacture and label medical devices as sterile at one establishment and ship the devices in interstate commerce for sterilization at another establishment, a practice that facilitates the processing of devices and is economically necessary for some firms. Under § 801.150(e)(1), manufacturers and sterilizers may sign an agreement containing the following: (1) Instructions for maintaining accountability of the number of units in each shipment, (2) acknowledgment that the devices that are nonsterile are being shipped for further processing, and (3) specifications for sterilization processing. This agreement allows the manufacturer to ship misbranded products to be sterilized without initiating regulatory action and provides FDA with a means to protect consumers from use of nonsterile products. During routine plant inspections, FDA normally reviews agreements that must be kept for 2 years after final shipment or delivery of devices (§ 801.150(a)(2)).

The respondents to this collection of information are device manufacturers and contract sterilizers. FDA's estimate of the reporting burden is based on actual data obtained from industry over the past several years where there are approximately 90 firms subject to this requirement. It is estimated that each of these firms on the average prepares 20 written agreements each year. This estimate varies greatly, from 1 to 100, because some firms provide sterilization services on a part-time basis for only one customer, while others are large facilities with many customers. The average time required to prepare each written agreement is estimated to be 4 hours. This estimate varies depending on whether the agreement is the initial agreement or an annual renewal, on the format each firm elects to use, and on the length of time required to reach agreement. The estimate applies only to those portions of the written agreement that pertain to the requirements imposed by this regulation. The written agreement generally also includes contractual agreements that are a customary and usual business practice. On the average, the total annual recordkeeping burden is 7,200 hours.

The recordkeeping requirements of § 801.150(a)(2) consist of making copies and maintaining the actual reporting requests which were required under the reporting section of this collection. To fulfill this requirement, FDA estimates it will take about 30 minutes to copy each package, for a total of 900 recordkeeping hours.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/21 CFR section	No. of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Agreement and labeling requirements, § 801.150(e)	90	20	1,800	4	7,200

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity/21 CFR section	No. of recordkeepers	No. of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Record retention, § 801.150(a)(2)	90	20	1,800	0.5 *	900

* (30 minutes)
[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: April 1, 2013.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2013–07916 Filed 4–4–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0370]

Agency Information Collection Activities; Proposed Collection; Comment Request; Export of Medical Devices; Foreign Letters of Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting requirements for firms that intend to export certain unapproved medical devices.

DATES: Submit either electronic or written comments on the collection of information by June 4, 2013.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *daniel.gittleson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Export of Medical Devices; Foreign Letters of Approval—(OMB Control Number 0910–0264)—Extension

Section 801(e)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 381(e)(2)) provides for the exportation of an unapproved device under certain circumstances if the exportation is not contrary to the public health and safety and it has the approval of the foreign country to which it is intended for export. Requesters communicate (either directly or through a business associate in the foreign country) with a representative of the foreign government to which they seek exportation, and written authorization must be obtained from the appropriate office within the foreign government approving the importation of the medical device. An alternative to obtaining written authorization from the foreign government is to accept a notarized certification from a responsible company official in the United States that the product is not in conflict with the foreign country's laws. This certification must include a statement acknowledging that the responsible company official making the certification is subject to the provisions of 18 U.S.C. 1001. This statutory provision makes it a criminal offense to knowingly and willingly make a false or fraudulent statement, or make or use a false document, in any manner within the jurisdiction of a department or agency of the United States. The respondents to this collection of information are companies that seek to export medical devices. FDA's estimate of the reporting burden is based on the experience of FDA's medical device program personnel.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/section of FD&C Act	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours	Total operating & maintenance costs
Foreign letter of approval—§ 801(e)(2)	38	1	38	3	114	$9,500

[1] There are no capital costs associated with this collection of information.

Dated: April 1, 2013.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2013–07915 Filed 4–4–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1093]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Additive Petitions and Investigational Food Additive Exemptions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by May 6, 2013.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0546. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3794, *Jonnalynn.capezzuto@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Food Additive Petitions and Investigational Food Additive Exemptions—(OMB Control Number 0910–0546)—Extension

Section 409(a) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 348(a)) provides that a food additive shall be deemed to be unsafe unless its use is permitted by a regulation which prescribes the condition(s) under which it may safely be used, or unless it is exempted by regulation for investigational use. Section 409(b) of the FD&C Act specifies the information that must be submitted by a petitioner in order to establish the safety of a food additive and to secure the issuance of a regulation permitting its use.

To implement the provisions of section 409 of the FD&C Act, procedural regulations have been issued under part 571 (21 CFR part 571). These procedural regulations are designed to specify more thoroughly the information that must be submitted to meet the requirement set down in broader terms by the FD&C Act. The regulations add no substantive requirements to those indicated in the FD&C Act, but attempt to explain these requirements and provide a standard format for submission to speed processing of the petition. Labeling requirements for food additives intended for animal consumption are also set forth in various regulations contained in parts 501, 573, and 579 (21 CFR parts 501, 573, and 579). The labeling regulations are considered by FDA to be cross-referenced to § 571.1, which is the subject of this same OMB clearance for food additive petitions.

With regard to the investigational use of food additives, section 409(j) of the FD&C Act provides that any food additive or any food bearing or containing such an additive, may be exempted from the requirements of this section if intended solely for investigational use by qualified experts. Investigational use of a food additive is typically to address the safety and/or intended physical or technical effect of the additive.

To implement the provisions of section 409(j) of the FD&C Act, regulations have been issued under § 570.17 (21 CFR 570.17). These regulations are designed to specify more thoroughly the information that must be submitted to meet the requirement set down in broad terms by the FD&C Act. Labeling requirements for investigational food additives are also set forth in various regulations contained in part 501. The labeling regulations are considered by FDA to be cross-referenced to § 570.17; which is the subject of this same OMB clearance for investigational food additive files. In the **Federal Register** of November 13, 2012, (75 FR 67655), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
Food Additive Petitions					
571.1(c) moderate category	1	1	1	3,000	3,000
517.1(c) complex category	1	1	1	10,000	10,000
517.1(c) complex category	2	2	4	1,300	5,200

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR Section	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
Total					18,200

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Section 571.1(c) Moderate Category: For a food additive petition without complex chemistry, manufacturing, efficacy, or safety issues, the estimated time requirement per petition is approximately 3,000 hours. An average of one petition of this type is received on an annual basis, resulting in a burden of 3,000 hours.

Section 571.1(c) Complex Category: For a food additive petition with complex chemistry, manufacturing, efficacy, and/or safety issues, the estimated time requirement per petition is approximately 10,000 hours. An average of one petition of this type is received on an annual basis, resulting in a burden of 10,000 hours.

Section 571.6: For a food additive petition amendment, the estimated time requirement per petition is approximately 1,300 hours. An average of four petitions of this type is received on an annual basis, resulting in a burden of 5,200 hours.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
Investigation Food Additive Files					
570.17 moderate category	9	1	9	1,500	13,500
570.17 complex category	4	1	4	5,000	20,000
Total					33,500

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Section 570.17 Moderate Category: For an investigational food additive file without complex chemistry, manufacturing, efficacy, or safety issues, the estimated time requirement per file is approximately 1,500 hours. An average of nine files of this type is received on an annual basis, resulting in a burden of 13,500 hours.

Section 570.17 Complex Category: For an investigational food additive file with complex chemistry, manufacturing, efficacy, and/or safety issues, the estimated time requirement per file is approximately 5,000 hours. An average of four files of this type is received on an annual basis, resulting in a burden of 20,000 hours.

Dated: April 1, 2013.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2013–07892 Filed 4–4–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Preparation for International Cooperation on Cosmetics Regulation; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA or we) is announcing a public meeting entitled, ''International Cooperation on Cosmetics Regulation (ICCR)—Preparation for ICCR–7 Meeting.'' The purpose of the meeting is to invite public input on various topics pertaining to the regulation of cosmetics. We may use this input to help us prepare for the ICCR–7 meeting that will be held in Japan on July 8 to 10, 2013.

DATES: *Date and Time:* The meeting will be held on May 8, 2013, from 2 p.m. to 4 p.m.

Location: The meeting will be held at the Food and Drug Administration, University Station Building, 4300 River Rd., Conference Room 3172 (third floor), College Park, MD 20740.

Contact Person: If you intend to participate in the meeting, you should register with Maria Rossana (Rosemary) Cook, Office of Cosmetics and Colors, Food and Drug Administration, 4300 River Rd., College Park, MD 20740, by email: *maria.cook@fda.hhs.gov* or Fax: 301–436–2975.

Registration and Requests for Oral Presentations: Send registration information (including your name, title, firm name, address, telephone number, fax number, and email address), written material, and requests to make an oral presentation, to the contact person by April 22, 2013.

If you need special accommodations due to a disability, please contact Maria Rossana (Rosemary) Cook (see *Contact Person*) by May 1, 2013.

You may present data, information, or views orally or in writing, on issues pending at the public meeting. Time allotted for oral presentations may be limited to 10 minutes or less for each presenter. If you wish to make an oral presentation, you should notify the contact person by April 22, 2013, and submit a brief statement of the general nature of the evidence or arguments that you wish to present, your name, address, telephone number, fax number, and email address, and indicate the approximate amount of time you need to make your presentation.

Transcripts: As soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It also may be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. You should send written requests for a hardcopy or CD–ROM transcript to the Division of Freedom of Information, (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

The purpose of the multilateral framework on the ICCR is to pave the way for the removal of regulatory obstacles to international trade while maintaining global consumer protection.

ICCR is a voluntary international group of cosmetics regulatory authorities from the United States, Japan, the European Union, and Canada. These regulatory authority members will enter into constructive dialogue with their relevant cosmetics industry trade associations and public advocacy groups. Currently, the ICCR members are: Health Canada; the European Directorate General for Health and Consumers; the Ministry of Health, Labor and Welfare of Japan; and the U.S. Food and Drug Administration. All decisions made by consensus will be compatible with the laws, policies, rules, regulations, and directives of the respective administrations and governments. Members will implement and/or promote actions or documents within their own jurisdictions and seek convergence of regulatory policies and practices. Successful implementation will need input from stakeholders.

You may present data, information, or views orally or in writing on issues pending at the public meeting. Time allotted for oral presentations may be limited to 10 minutes or less for each presenter. If you wish to make an oral presentation, you should notify the contact person by April 22, 2013, and submit a brief statement of the general nature of the evidence or arguments that you wish to present, your name, address, telephone number, fax number, and email address, and indicate the approximate time you need to make your presentation. If you need special accommodations due to a disability, please contact Maria Rossana (Rosemary) Cook (*see Contact Person*) by May 1, 2013.

We will make the agenda for the public meeting available on the Internet at: *http://www.fda.gov/Cosmetics/InternationalActivities/Conferences MeetingsWorkshops/International CooperationonCosmeticsRegulations ICCR/default.htm.* We may use the information that you provide to us during the public meeting to help us prepare for the July 8 to 10, 2013 ICCR–7 meeting.

Dated: April 1, 2013.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2013–07949 Filed 4–4–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Vaccines and Related Biological Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on May 8, 2013, from 1 p.m. to approximately 4 p.m.

Location: Rockwall II, Conference Room 1033, 5515 Security Lane, Rockville, MD 20852. The public is welcome to attend the meeting at the specified location where a speakerphone will be provided. Public participation in the meeting is limited to the use of the speakerphone in the conference room.

Contact Person: Donald W. Jehn or Denise Royster, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On May 8, 2013, the committee will meet in open session to hear updates of the research programs in the Laboratory of DNA Viruses, Division of Viral Products, Office of Vaccines Research and Review, Center for Biologics Evaluation and Research, FDA.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: On May 8, 2013, from 1 p.m. to approximately 3:20 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before May 1, 2013. Oral presentations from the public will be scheduled between approximately 2:20 p.m. and 3:20 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before April 23, 2013. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by April 24, 2013.

Closed Committee Deliberations: On May 8, 2013, from approximately 3:20 p.m. to approximately 4 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The committee will discuss

the report of the intramural research programs and make recommendations regarding personnel staffing decisions.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Donald W. Jehn or Denise Royster at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 2, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013–07961 Filed 4–4–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

2013 Medical Countermeasures Initiative Regulatory Science Symposium

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA) is announcing the following meeting: 2013 Medical Countermeasures initiative (MCMi) Regulatory Science Symposium. The symposium is intended to provide a forum for the exchange of ideas for medical countermeasure development, highlight work on regulatory science as it applies to the development and advancement of medical countermeasures, facilitate innovative directions, and inform stakeholders on medical countermeasure-related scientific progress and accomplishments.

Dates and Times: The symposium will be held on May 29 and May 30, 2013, from 9 a.m. to 5 p.m., and on May 31, 2013, from 9 a.m. to 12 noon. Persons interested in attending the symposium in person or viewing via Webcast must register by May 24, 2013, at 5 p.m. EST.

Location: The symposium will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Entrance for the symposium participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Contact: Rakesh Raghuwanshi, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4283, Silver Spring, MD 20993, 301–796–4769, Fax: 301–847–8615, email: *AskMCMi@fda.hhs.gov.*

Registration: If you wish to attend the symposium or view via Webcast, you must register at *http://www.fda.gov/medicalcountermeasures* by May 24, 2013, at 5 p.m. EST. When registering, you must provide the following information: (1) Your name, (2) title, (3) company or organization (if applicable), (4) mailing address, (5) phone number, and (6) email address.

There is no fee to register for the symposium and registration will be on a first-come, first-served basis. Early registration is recommended because seating is limited.

If you need special accommodations due to a disability, please enter pertinent information in the ''Notes'' section of the electronic registration form when you register.

Date: April 1, 2013.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2013–07893 Filed 4–4–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Society of Clinical Research Associates-Food and Drug Administration: Food and Drug Administration Clinical Trial Requirements, Regulations, Compliance, and Good Clinical Practice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of conference.

SUMMARY: The Food and Drug Administration (FDA) is announcing an educational conference co-sponsored with the Society of Clinical Research Associates (SOCRA). The conference on FDA's clinical trial requirements is designed to aid the clinical research professional's understanding of the mission, responsibilities, and authority of FDA and to facilitate interaction with FDA representatives. The program will focus on the relationships among FDA and clinical trial staff, investigators, and institutional review boards (IRBs). Individual FDA representatives will discuss the informed consent process and informed consent documents, and regulations relating to drugs, devices, and biologics, as well as inspections of clinical investigators, IRBs, and research sponsors.

DATES: *Date and Time:* The conference will be held on May 15 and 16, 2013, from 8 a.m. to 5 p.m.

Location: The conference will be held at the Renaissance Seattle Hotel, 515 Madison St., Seattle, WA 98104.

Contact Person: Jane Kreis, Food and Drug Administration, 1301 Clay St., Suite 1180N, Oakland, CA 94612, 510–287–2708, FAX: 510–287–2739; or Society of Clinical Research Associates (SOCRA), 530 West Butler Ave., Suite 109, Chalfont, PA 18914, 800–762–7292, FAX: 215–822–8633, email: *SoCRAmail@aol.com,* Web site: *www.socra.org.*

Registration and Meeting Information: See SOCRA Web site, *www.SoCRA.org. http://www.socra.org/html/FDA_Conference.htm.* Registrations fees are as follows: $575.00 for SOCRA members; $650.00 for nonmembers (includes membership); $450.00 for Federal Government members; $525.00 for Federal Government nonmembers; FDA employee rate is fee-waived. The registration fee will cover actual expenses including refreshments, lunch, materials, and speaker expenses. If you need special accommodations due to a disability, please contact Jane Kreis (see *Contact Person*) at least 10 days in advance.

SUPPLEMENTARY INFORMATION: The public workshop helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health. The workshop will provide those engaged in FDA-regulated (human) clinical trials with information on a number of topics concerning FDA requirements related to informed consent, clinical investigation requirements, institutional review board inspections, electronic record

requirements, and investigator-initiated research. Topics for discussion include the following: (1) What FDA Expects in a Pharmaceutical Clinical Trial; (2) Adverse Event Reporting—Science, Regulation, Error, and Safety; (3) Part 11 Compliance—Electronic Signatures; (4) Informed Consent Regulations; (5) IRB Regulations and FDA Inspections; (6) Keeping Informed and Working Together; (7) FDA Conduct of Clinical Investigator Inspections; (8) Meetings With FDA: Why, When, and How; (9) Investigator-Initiated Research; (10) Medical Device Aspects of Clinical Research; (11) Working With FDA's Center for Biologics Evaluation and Research; and (12) The Inspection is Over—What Happens Next? Possible FDA Compliance Actions.

Extended periods of question and answer and discussion have been included in the program schedule. This program offers 13.3 hours of continuing medical education (CME) and continuing nursing education (CNE) credit. *CME for Physicians:* The Society of Clinical Research Associates is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. *CNE for Nurses:* Society of Clinical Research Associates is an approved provider of continuing nursing education by the Pennsylvania State Nurses Association (PSNA), an accredited approver by the American Nurses Credentialing Center's Commission (ANCC) on Accreditation. ANCC/PSNA Provider Reference Number: 205–3–A–09.

FDA has made education of the drug and device manufacturing community a high priority to help ensure the quality of FDA-regulated drugs and devices. The workshop helps to achieve objectives set forth in section 406 of the FDA Modernization Act of 1997 (21 U.S.C. 393), which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The workshop also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), as outreach activities by Government agencies to small businesses.

Dated: April 1, 2013.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2013–07894 Filed 4–4–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0012]

Pediatric Device Consortia Grant Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of grant funds for the support of the Office of Orphan Products Development (OOPD) Pediatric Device Consortia (PDC) Grant Program. The goal of the PDC Grant Program is to facilitate the development, production, and distribution of pediatric medical devices. The PDC will provide grants to nonprofit consortia which provide expert advising and support services to innovators of pediatric devices. These services should include business and regulatory consulting as well as device testing capabilities. This program is intended to further the development of multiple pediatric devices; thus, grants are not awarded to support the development of a single device project.

Although administered by the OOPD, this grant program is intended to encompass devices that could be used in all pediatric conditions and diseases, not just rare diseases. The pediatric population (neonates, infants, children, and adolescents) includes patients who are 21 years of age or younger at the time of diagnosis or treatment.

DATES: Important dates are as follows:

1. The application due date is June 1, 2013.
2. The anticipated start date is September, 2013.
3. The opening date is May 1, 2013.
4. The expiration date is June 2, 2013.

ADDRESSES: Submit the paper application to: Vieda Hubbard, Grants Management (HFA–500), 5630 Fishers Lane, Rm. 2034, Rockville, MD 20857. For more information, see section III of the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT:

Linda C. Ulrich, Director, Pediatric Device Consortia Grants Program, Food and Drug Administration, Bldg. 32, Rm. 5271, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–8660; or

Vieda Hubbard, Grants Management Specialist, Office of Acquisitions & Grant Services, Food and Drug Administration, 5630 Fishers Lane, Rm. 2034, Rockville, MD 20857, 301–827–7177.

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please refer to the full FOA located at *http://grants.nih.gov/grants/guide/* or *http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/default.htm.*

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

RFA–FD–13–010

93.103

A. Background

The development of pediatric medical devices currently lags behind the development of devices for adults. Pediatric patients often differ from adults in terms of their size, growth, development, body chemistry, and disease propensity, adding to the challenges of pediatric device development. There currently exists a great need for pediatric medical devices, including devices designed originally for pediatric patients as well as existing adult devices adapted for pediatric use. Recent passage of the Food and Drug Administration Safety and Improvement Act (FDASIA) (Pub. L. 112–144) reauthorized support of section 305 of the Pediatric Medical Device Safety and Improvement Act of 2007 (Pub. L. 110–85), which requires HHS to provide demonstration grants to nonprofit consortia to promote pediatric device development. While the consortia themselves are nonprofit entities, their contacts and membership can include for-profit partners.

B. Research Objectives

The Pediatric Device Consortia Grant Program aims to fund networks of pediatric medical device advisors who are able to provide a platform of experienced regulatory, business planning, and device development services (such as intellectual property advising; prototyping; engineering; laboratory and animal testing; grant writing; and clinical trial design) to help foster and guide the advancement of medical devices for pediatric patients. A successful PDC brings together individuals and institutions that can support pediatric medical device progression through all stages of development—concept formation, prototyping, preclinical, clinical, manufacturing, marketing, and commercialization. The consortia are expected to support a mix of projects at all stages of development, particularly the later stages of clinical, manufacturing, and marketing.

Specifically, the consortia will facilitate the development, production, and distribution of pediatric medical devices by: (1) Encouraging innovation and connecting qualified individuals with pediatric device ideas with potential manufacturers; (2) mentoring and managing pediatric device projects through the development process, including product identification, prototype design, device development, and marketing; (3) connecting innovators and physicians to existing Federal and non-Federal resources; (4) assessing the scientific and medical merit of proposed pediatric device projects; and (5) providing assistance and advice as needed on business development, personnel training, prototype development, and post-marketing needs.

C. Eligibility Information

The grants are available to any domestic, public or private, nonprofit entity (including State and local units of government). Federal agencies that are not part of HHS may apply. Agencies that are part of HHS may not apply. Organizations that engage in lobbying activities, as described in section 501(c)(4) of the Internal Revenue Code of 1968, are not eligible to receive grant awards.

II. Award Information/Funds Available

A. Award Amount

The estimated amount of funds available for support of four to five consortia awarded as a result of this announcement is $3 million for fiscal year 2013. Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary. Although PDC financial plans include support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications.

B. Length of Support

Grants will be awarded on a competitive basis up to $750,000 in total (direct plus indirect) costs per year for up to 5 years, contingent upon favorable annual review and an additional mid-cycle review after 2½ years of funding.

III. Paper Application, Registration, and Submission Information

To submit a paper application in response to this FOA, applicants should first review the full announcement located at *http://grants.nih.gov/grants/guide/* or *http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/default.htm.* (FDA has verified the Web site addresses throughout this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register.**) Persons interested in applying for a grant may obtain an application at *http://grants.nih.gov/grants/forms.htm.* For all paper application submissions, the following steps are required:

- Step 1: Obtain a Dun and Bradstreet (DUNS) Number.
- Step 2: Register With System for Award Management.

Steps 1 and 2, in detail, can be found at *http://www07.grants.gov/applicants/organization_registration.jsp.* After you have followed these steps, submit paper applications to: Vieda Hubbard, Grants Management Specialist, Office of Acquisitions & Grant Services, 5630 Fishers Lane, Rm. 2034, Rockville, MD 20857, phone: 301–827–7177.

Dated: April 2, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–07948 Filed 4–4–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0345]

Food and Drug Administration/National Institutes of Health/National Science Foundation Public Workshop on Computer Methods for Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing its fifth public workshop on Computer Methods for Medical Devices entitled ''FDA/NIH/NSF Workshop on Computer Models and Validation for Medical Devices.'' The purpose of the workshop is to present, discuss, and receive input on an FDA library of models and data relevant to medical devices (day 1) and present, discuss, and receive input on a strategy to assess the credibility of computer models used to evaluate medical devices (day 2).

DATES: *Dates and Times:* The workshop will be held on June 11 and 12, 2013, from 8:30 a.m. to 5:30 p.m.

Location: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to: *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Contact Persons: Donna Lochner, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 62, Rm. 3220, Silver Spring, MD 20993, 301–796–6309, *Donna.Lochner@fda.hhs.gov;* or Tina M. Morrison, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1272, Silver Spring, MD 20993, 301–796–6310, *Tina.Morrison@fda.hhs.gov.*

Registration: Registration is free and will be on a first-come, first-served basis. Persons interested in attending this public workshop must register online by 4 p.m. on May 31, 2013. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 8 a.m.

To register for the public workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* Select this public workshop from the posted events list. Please provide complete contact information for each attendee, including name, title, affiliation, mailing address, email address, and telephone number. Those without Internet access should contact Susan Monahan to register (301–796–5661 or *Susan.Monahan@fda.hhs.gov*). Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

If you need special accommodations due to a disability, please contact Susan Monahan (*Susan.Monahan@fda.hhs.gov* or 301–796–5661) no later than May 28, 2013.

Streaming Webcast of the Public Workshop: This workshop will also be available via Webcast. Persons interested in viewing the Webcast must register online by 4 p.m. on May 31, 2013. Early registration is recommended because Webcast connections are limited. Organizations are requested to

register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and connection access information after June 4, 2013. If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm*. To get a quick overview of the Connect Pro program, visit *http://www.adobe.com/go/connectpro_overview*. (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

Comments: FDA is holding this public workshop to obtain information on the topics identified in Section II of this document. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public workshop topics. The deadline for submitting comments related to this public workshop is July 10, 2013.

Regardless of attendance at the public workshop, interested persons may submit either electronic comments to *http://www.regulations.gov* or written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Please identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

The Center for Devices and Radiological Health (CDRH) believes that computer modeling and simulation (M&S) has the potential to substantially augment traditional models used to evaluate medical devices; i.e., animal, bench, and human models, and to accelerate and streamline the total product life cycle of a medical device. The use of computer models to simulate multiple use conditions and to visualize and display complex processes and data can revolutionize the way medical outcomes and medical devices are understood. Nonproprietary computer models could benchmark device performance, yet lack of access to biomedical data to construct the models and rigorous methods to validate the models limit their credibility and use. Before substantial advances in the use of M&S for regulatory decision making can be attained, a strategy and consistent framework to assess the credibility of M&S is needed. Moreover, to foster good science for M&S in the medical device community, CDRH needs to leverage the expertise in industry and academia to develop a strategy to scientifically assess the credibility of M&S and to develop a resource to publicize biomedical data, models and their validation for regulatory use.

II. Topics

Historically, M&S have been used as development and design optimization tools, rather than methods by which performance of final devices can be demonstrated. Further, modeling studies that are submitted to the Agency are supplemental and complement animal, bench and human testing provided in:

- Investigational Device Exemptions (investigational devices),
- 510(k) notifications (class II devices), and
- Pre-Market Approval applications (class III devices).

Some of the challenges with the current uses of M&S are:

- Reports typically lack sufficient details for adequate assessment because there are no reporting standards for computational modeling,
- Lack of sensitivity and uncertainty analyses for crucial input parameters, such as geometry, physical properties, boundary conditions,
- Lack of adequate validation to support the use of the computational model, and
- Lack of complete understanding of physiological loads and variations in patient populations.

Adequate verification and validation (V&V) are necessary in order to foster confidence and wider acceptance of M&S for use in medical device evaluation. Therefore, CDRH, in collaboration with the American Society of Mechanical Engineers, has been drafting a guide on the ''Verification and Validation of Computational Modeling for Medical Devices.'' The strategy is meant to create a framework for determining the risk associated with using a computational model in a specific context of use (COU) to inform decision making and for determining ''how much'' V&V is necessary to support the model for its COU. The two main components of this strategy are the Risk Assessment Matrix and the Credibility Assessment Matrix. Both of these tools will be presented and discussed at the workshop. Note that these tools are still in DRAFT format.

The workshop will also describe and discuss FDA's efforts to create a resource or Library of biomedical data and models that can be used in regulatory applications. Key features and questions related to development of the Library and curation of data and models for the Library will be discussed. The goal of the FDA/NIH/NSF Workshop on Computer Modeling and Validation for Medical Devices is to discuss and receive input on these tools to enhance their utility in the community.

Dated: April 1, 2013.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2013–07923 Filed 4–4–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301–496–7057; fax: 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Highly Potent and Selective Deubiquitinating Enzyme Inhibitor

Description of Technology: Available for licensing are inhibitors that target the USP1/UAF1 deubiquitnating enzyme (DUB) complex. The FDA approval and commercial success of

Velcade®, a small molecule proteasome inhibitor, has established the ubiquitin-proteasome system (UPS) as a valid target for anticancer treatment. However, proteasome inhibitors in general suffer from a narrow therapeutic index and acquired resistance. A promising alternative to proteasome inhibition has been to target the enzymes upstream of proteasome-mediated protein degradation, i.e. the ubiquitin conjugation and deconjugation, to generate more specific, less toxic therapeutic agents. The investigators have developed small molecules that target the USP1/UAF1 DUB complex that acts upstream of UPS and has been implicated in the DNA damage response. These compounds are the most potent and selective DUB inhibitors reported to date. Moreover, the inhibitors act synergistically with cisplatin, a DNA damaging anti-cancer drug, to overcome chemoresistance and enhance cytotoxicity. These results suggest the inhibitors may also improve the efficacy and potency of other commonly prescribed chemotherapeutic agents that are known to induce DNA damage.

Potential Commercial Applications:

- Method to treat cancer
- Method to overcome chemoresistance to cisplatin
- Pharmaceutical compositions

Competitive Advantages:

- Represents the most potent and selective DUB inhibitor reported to date.
- Promising alternative to proteasome inhibition offering the potential of more selective and less toxic therapeutic agents.
- Acts synergistically with DNA damaging agents to overcome chemoresistance.

Development Stage:

- Early-stage
- In vitro data available

Inventors: David Maloney (NCATS), Andrew Rosenthal (NCATS), Ajit Jadhav (NCATS), Thomas Dexheimer (NCATS), Anton Simeonov (NCATS), Zhihao Zhuang (University of Delaware), Qin Liang (University of Delaware), Diane Luci (NCATS)

Intellectual Property: HHS Reference No. E–043–2013/0—US Provisional Application No. 61/747,052 filed 28 December 2012

Related Technologies:

- HHS Reference No. E–208–2007/0—US Patent Application No. 12/669,361 filed 15 January 2010
- HHS Reference No. E–156–2012/0—US Provisional Application No. 61/692,560 filed 23 August 2012
- HHS Reference No. E–231–2002/0—US Patent No. 7,498,336 issued 3 March 2009
- HHS Reference No. E–070–2005/0—US Patent No. 8,242,160 issued 14 June 2012 and US Patent Application No. 13/547,417 filed 12 July 2012

Licensing Contact: Jennifer Wong, M.S.; 301–435–4633; *wongje@mail.nih.gov.*

Collaborative Research Opportunity: The National Center for Advancing Translational Sciences is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize this invention. For collaboration opportunities, please contact Lili Portilla at *lili.portilla@nih.gov.*

Therapeutic Applications of a Carboxy-Terminal RTDL Motif

Description of Technology: Mesencephalic Astrocyte-derived Neurotrophic Factor (MANF) is a secreted neurotrophic factor with known anti-neurodegenerative properties. The inventors discovered that the C-terminal RTDL motif of MANF is involved in the anti-degenerative properties of MANF and association of extracellular MANF with the cell surface. Isolated peptides, including the C-terminal RTDL motif of MANF, potentially can be used as a treatment for neurodegenerative disorders and ischemia.

Potential Commercial Applications: Treating neurodegenerative diseases, such as Alzheimer's disease, Parkinson's disease, Huntington disease, etc.

Competitive Advantages: Secreted novel peptides.

Development Stage:

- Early-stage
- Pre-clinical
- In vitro data available

Inventors: Brandon K Harvey, et al. (NIDA)

Intellectual Property: HHS Reference No. E–249–2012/0—US Provisional Application 61/732, 241 filed 30 Nov 2012

Licensing Contact: Betty B. Tong, Ph.D.; 301–594–6565; *tongb@mail.nih.gov*

HIV-Neutralizing Polypeptides: A Novel Use for Platelet Factor 4 or Its Derivatives

Description of Technology: The subject invention describes the method for using Platelet Factor 4 (PF4), also called CXCL4, to inhibit HIV viral entry by blocking GP120 independent of HIV receptor. It also demonstrates that the active polypeptide fragment(s) of PF–4 could be used to identify potential peptide mimics or small molecules that could be used to inhibit HIV infection. PF4 and/or its derivatives may be developed as a systemic therapy or preventive measure using topical applications, such as microbicides. In addition, CXCL4 serum/plasma testing could be used as a clinical marker of HIV disease status to predict/monitor the efficacy of treatment and determine the prognosis of a subject with HIV infection.

Potential Commercial Applications:

- Treatment and prevention of HIV–1 infection.
- Topical application as microbicides.
- A vaccine adjuvant to boost the vaccine efficacy.
- A clinical marker of HIV disease status or to predict/monitor the efficacy of treatment or vaccines.

Competitive Advantages:

- A new HIV–1 inhibitory molecule that acts through a new inhibitory mechanism.
- Any potential derivative or mimicking compound would be unique and have the advantage of hitting a previously unrecognized molecular target in the HIV life cycle.

Development Stage:

- Early-stage
- In vitro data available

Inventors: Paolo Lusso and David J. Auerbach (NIAID)

Publication: Auerbach DJ, et al. Identification of the platelet-derived chemokine CXCL4/PF–4 as a broad-spectrum HIV–1 inhibitor. Proc Natl Acad Sci USA 2012 Jun 12;109(24):9569–74. [PMID 22645343]

Intellectual Property: HHS Reference No. E–140–2012/0—US Application No. 61/649,150 filed 19 Jun 2012

Related Technology: The CXCL4 sequence is in the public domain.

Licensing Contact: Sally Hu, Ph.D., MBA; 301–435–5606; *hus@mail.nih.gov.*

Polarimetric Accessory for Colposcope

Description of Technology: Available for licensing and commercial development is a colposcope accessory device that compensates and resolves tissue borne specular reflections. In medical diagnostic procedures for examining the cervix and the tissues of the vagina and vulva, long working-distance (−30 cm) lighted binocular microscope (colposcope) that provide up to 25x optical magnification are used to create an illuminated magnified view. Speculum dilations can give rise to specular reflections from the tissue surface. The present polarimetric accessory overcomes this limitation and enhances the visibility of subsurface structures of the scattering object. Linearly polarized light is used for cervical illumination and imaging is

performed through an additional polarizer that separates the specularly reflected light from the diffusely backscattered light, which originates in deeper tissue layers, allowing enhanced imaging of the hidden subsurface tissue structure (texture). The region of interest is illuminated by linearly polarized light, and backscattered light passes through the polarization filter to be detected by a digital camera. A custom optical design preserves the polarization state of the backscattered light in the microscope, without interfering with the standard optical path and operation of the microscope, including its binocular system. Special algorithms to visualize regions of statistical similarity in the image have been developed. Though the diffusely backscattered light presents only a small fraction of the detected light, its analysis, using the customized design and image processing procedures, provides useful information about internal structures of biological tissues. The polarimetric accessory includes a linear polarizer for the illuminating beam, two beam splitters for preserving polarization state, lens system for imaging, polarization analyzer, band-pass optical filter, digital camera, and electronic triggering system.

Potential Commercial Applications: Gynecological examinations

Competitive Advantages:

- Image quality
- Resolution of tissue structures at close microscopic distances

Development Stage: Prototype

Inventors: Amir Gandjbakhche (NICHD), Victor Chernomordik (NICHD), Moinuddin Hassan (NICHD), Alexander Sviridov (NICHD), Zachary Alissi (NICHD), Paul Smith (NIBIB), Albert Boccara (NICHD)

Publications:

1. Jacques SL, et al. Imaging superficial tissues with polarized light. Lasers Surg Med. 2000;26(2):119–29. [PMID 10685085]

2. Jacques SL, et al. Imaging skin pathology with polarized light. J Biomed Opt. 2002 Jul;7(3):329–40. [PMID 12175282]

3. Ramella-Roman JC, et al. Design, testing, and clinical studies of a handheld polarized light camera. J Biomed Opt. 2004 Nov–Dec;9(6):1305–10. [PMID 15568952]

4. Sviridov AP, et al. ''Analysis of Biological Tissue Textures Using Measurements of Backscattered Polarized Light'' (presented at the Optical Society of America—Biomedical Optics Topical Meeting, Fort Lauderdale, Florida, March 2006).

5. Sviridov AP, et al. Visualization of biological texture using correlation coefficient images. J Biomed Opt. 2006 Nov–Dec;11(6):060504. [PMID 17212522]

Intellectual Property: HHS Reference No. E–084–2012—US Provisional Patent Application No. 61/620,295 filed 04 Apr 2012

Licensing Contact: Michael A. Shmilovich, Esq., CLP; 301–435–5019; *shmilovm@mail.nih.gov*

CpG Oligonucleotides Treatment To Prevent Chemotherapy-Induced Pulmonary Toxicity

Description of Technology: Bleomycin (BLM) is a chemotherapy agent used to treat multiple types of cancer, but its side effects are life threatening for some patients. About 20% of patients undergoing BLM chemotherapy develop interstitial pneumonitis which may develop to life threatening fibrosis. In such cases, BLM chemotherapy cannot be continued.

This invention identifies a method of pre-treatment using immunostimulatory CpG Oligonucleotide (ODN) molecules to prevent chemotherapy-induced pulmonary toxicity. Administration of certain ODN molecules induces inflammation via stimulation of inflammatory genes (Toll-like receptor 9/TLR9). This stimulation is subsequently down-regulated. This technology makes use of this counter regulatory mechanism to reduce the side effects of chemotherapy agents, such as BML. A properly timed pre-administration of ODN molecules, prior to BML therapy, prevents the lethal side effect of BLM-induced pulmonary inflammation and down-regulates promoters of BLM toxicity (IL–17A and TGF-beta1). Because toxicity from pulmonary inflammation is a side effect limiting use of many chemotherapeutic agents and ODN molecules are relatively inexpensive and have a favorable safety profile, this technology may be useful to improve treatment protocols for many chemotherapy agents.

Potential Commercial Applications: Therapeutic to reduce harmful side effects of pulmonary inflammation caused by chemotherapy.

Competitive Advantages:

- Pulmonary toxicity during chemotherapy is dangerous side effect, this technology uses ODN molecules that are relatively inexpensive and have a favorable safety profile to reduce this side effect.
- This technology may increase the safety and availability of many chemotherapy treatments.

Development Stage:

- Early-stage
- In vivo data available (animal)

Inventors: Dennis Klinman and Takeshi Kinjo (NCI)

Publication: Kinjo T, et al. The counter regulatory response induced by CpG oligonucleotides prevents bleomycin induced pneumopathy. Respir Res. 2012 Jun 18;13:47. [PMID 22708497]

Intellectual Property: HHS Reference No. E–077–2012/0—U.S. Provisional Patent Application No. 61/643,088 filed 04 May 2012

Licensing Contact: Edward (Tedd) Fenn; 301–435–5031; *fenned@mail.nih.gov*

Collaborative Research Opportunity: The National Cancer Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize CpG oligonucleotides for use to down-modulate inflammatory reactions. For collaboration opportunities, please contact John D. Hewes, Ph.D. at *hewesj@mail.nih.gov.*

Dated: April 1, 2013.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2013–07917 Filed 4–4–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Management of the Primate Aging Database

Date: April 23, 2013.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Elaine Lewis, Ph.D., Scientific Review Branch, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301–402–7707, *elainelewis@nia.nih.gov.*

(Catalogue of Federal Domestic Assistance Program No. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: April 1, 2013.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–07904 Filed 4–4–13; 8:45 am]

BILLING CODE 4140–01–P

Department of Health and Human Services

National Institutes of Health

Office of the Director, National Institutes of Health, Notice of Meeting

Notice is hereby given of a meeting scheduled by the Deputy Director for Intramural Research at the National Institutes of Health (NIH) with the Chairpersons of the Boards of Scientific Counselors. The Boards of Scientific Counselors are advisory groups to the Scientific Directors of the Intramural Research Programs at the NIH. This meeting will take place on April 29, 2013, from 10:00 a.m. to 2:00 p.m., at the NIH, 1 Center Drive, Bethesda, MD, Building 1, Room 151. The meeting will include a discussion of policies and procedures that apply to the regular review of NIH intramural scientists and their work.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Margaret McBurney, Office of Intramural Research, NIH, Building 1, Room 160, Telephone (301) 496–1921, Fax (301) 402–4273, or email *mmcburney@od.nih.gov* in advance of the meeting.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Dated: March 29, 2013.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–07906 Filed 4–4–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review Amended; Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, March 29, 2013, 01:00 p.m. to March 29, 2013, 05:00 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD, 20817 which was published in the **Federal Register** on March 12, 2013, 78 FR Pg. 15729.

The meeting with be held on April 4, 2013 instead of March 29, 2013 at 1:00 p.m. and will end at 5:00 p.m. The meeting location remains the same. The meeting is closed to the public.

Dated: March 29, 2013.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–07899 Filed 4–4–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Diabetes, Metabolism and Obesity.

Date: April 11, 2013.

Time: 8:00 a.m. to 9:00 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Dianne Hardy, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6175, MSC 7892, Bethesda, MD 20892, 301–435–1154, *dianne.hardy@nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: April 1, 2013.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–07900 Filed 4–4–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Hypoxia and Respiration.

Date: April 30, 2013.

Time: 9:00 a.m. to 11:30 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Room 7206, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Shelley S. Sehnert, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7206, Bethesda, MD 20892–7924, 301–435–0303, *ssehnert@nhlbi.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung

Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: March 29, 2013.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–07903 Filed 4–4–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the meeting of the Council of Councils.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

A portion of the meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4), and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Council of Councils.

Open: May 14, 2013, 8:30 a.m. to 2:00 p.m.

Agenda: DPCPSI Update, Overview of Common Fund Epigenomics Program, Scientific Presentation, NIH Update, Concept Clearance and Discussion.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.

Closed: May 14, 2013, 2:00 p.m. to 3:10 p.m.

Agenda: Review of grant applications.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.

Open: May 14, 2013, 3:10 p.m. to 5:00 p.m.

Agenda: Council Business Matters, Update on Implementation of NIH Policy on the Use of Chimpanzees in NIH-Supported Research, Update on Office of Disease Prevention.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.

Contact Person: Robin Kawazoe, Executive Secretary, Division of Program Coordination, Planning, and Strategic Initiatives, Office of the Director, NIH, Building 1, Room 260, Bethesda, MD 20892, 301–402–9852.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person. Information is also available on the Council of Council's home page at *http://dpcpsi.nih.gov/council/* where an agenda and proposals to be discussed will be posted before the meeting date.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: April, 1, 2013.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–07905 Filed 4–4–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of A Start-Up Commercialization Exclusive License: The Development of Fenoterol Analogues for the Treatment of Brain and Hepatocellular Cancers

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant to Nova Therapeutics LLC of a start-up exclusive commercialization license to practice the inventions embodied in the following US Provisional Patent Application (and all domestic and foreign counterparts claiming priority to it): Serial No. 61/651,961, filed May 25, 2012, entitled, ''Methods of Regulating Cannabinoid Receptor Activity-related Disorders and Diseases'' [HHS Ref. E–139–2012/0–US–01]. The patent rights in this invention have been assigned to the Government of the United States of America.

The prospective start-up exclusive commercialization license territory may be worldwide, and the field of use may be limited to:

A worldwide exclusive license to the Patent Rights for research, development, manufacture, distribution, sale, and use in humans for the treatment of brain cancer or hepatocellular cancer within the Licensed Territory, exclusive of (*R,R'*)-4'-methoxy-1-napthylfenoterol (MNF), (*R,S'*)-4'-methoxy-1-napthylfenoterol, (*R,R'*)-ethylMNF, (*R,R'*)-napthylfenoterol, (*R,S'*)-napthylfenoterol, (*R,R'*)-ethyl-napthylfenoterol, and (*R,R'*)-4'-amino-1-napthylfenoterol, (*R,R'*)-4'-hydroxy-1-napthylfenoterol, (*R,R'*)-4-methoxy-ethylfenoterol, (*R,R'*)-methoxyfenoterol, (*R,R'*)-ethylfenoterol, and (*R,R'*)-fenoterol, and the respective stereoisomers of these compounds.

DATES: Only written comments or applications for a license (or both) which are received by the NIH Office of Technology Transfer on or before April 22, 2013 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive commercialization license should be directed to: Patrick McCue, Ph.D., Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–5560; Facsimile: (301) 402–0220; Email: *mccuepat@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: This invention concerns the discovery by the inventors that specific fenoterol analogues are cannabinoid receptor activators that can inhibit one or more signs or symptoms (such as growth) associated with a tumor that expresses a cannabinoid receptor. Using this discovery, the inventors developed the disclosed methods of treating a tumor expressing a cannabinoid receptor.

The prospective start-up exclusive commercialization license is being considered under the small business initiative launched on 1 October 2011, and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective start-up exclusive commercialization license

may be granted unless the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7 within fifteen (15) days from the date of this published notice.

Complete applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive evaluation option license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: April 1, 2013.

Richard U. Rodriguez,

Director, Division of Technology Development & Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2013–07907 Filed 4–4–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Literature Review Approach ''Identifying Research Needs for Assessing Safe Use of High Intakes of Folic Acid''; Request for Information and Comments

SUMMARY: The National Toxicology Program (NTP) at the National Institute of Environmental Health Sciences (NIEHS) in conjunction with the NIH Office of Dietary Supplements (ODS) is planning a workshop to identify research needs based on consideration of the state of the science related to the safe use of high intakes of folic acid. The NTP and the ODS invite comments on an approach document, ''Identifying Research Needs for Assessing Safe Use of High Intakes of Folic Acid,'' for review of the pertinent literature. The document is available on the NTP Folic Acid Request for Information (RFI) Web site (*http://ntp.niehs.nih.gov/go/38143*). Information gathered through this request will be used in prioritizing topics for the state of the science workshop.

DATES: The deadline for receipt of information and comments is May 28, 2013.

ADDRESSES: Comments should be submitted at *http://ntp.niehs.nih.gov/go/38143*.

FOR FURTHER INFORMATION CONTACT: Abee L. Boyles, Ph.D., Health Scientist, Office of Health Assessment and Translation, Division of the NTP, NIEHS, PO Box 12233, MD: K2–04, Research Triangle Park, NC 27709; telephone: (919) 541–7886; fax: (301) 480–3230; email: *abee.boyles@nih.gov*. Courier address: NIEHS, Room 2158, 530 Davis Drive, Morrisville, NC 27560 or Regan Bailey, Ph.D., R.D., Nutritional Epidemiologist, ODS, NIH, 6100 Executive Blvd., Room 3B01, Bethesda, MD 20892–7517; telephone: (301) 496–0187; fax: (301) 480–1845; email: *regan.bailey@nih.gov*.

SUPPLEMENTARY INFORMATION:

Background: The NTP in conjunction with the NIH ODS is planning a workshop to identify research needs based on consideration of the state of the science related to the safe use of high intakes of folic acid. The benefit of supplemental folic acid for pregnant women to prevent neural tube defects in their children is well established; at the same time, there is interest in understanding potential adverse health impacts from high intakes of folic acid. This project aims to identify research needs and inform the development of a research agenda for evaluating the safe use of high intakes of folic acid.

Due to the vastness of the research on folate and folic acid, screening of the literature was undertaken to identify the potential adverse health effects for which further research might be warranted. An approach document, ''Identifying Research Needs for Assessing Safe Use of High Intakes of Folic Acid,'' is available on the RFI Web site (*http://ntp.niehs.nih.gov/go/38143*) and should be referenced in responding to the RFI. This document (1) outlines the approach used to screen the literature, (2) describes the results of the screening effort, and (3) proposes a list of health outcomes for discussion at the workshop. As background for the workshop, a literature review document on these health outcomes will be prepared using systematic review methodology.

Humans require folate, a water-soluble B-complex vitamin, for the synthesis of nucleic acids and to provide methyl groups for biochemical reactions within cells. These functions are needed for everyday growth and cell division, including during critical periods of rapid growth and cell division such as embryonic development. Thus, folate is necessary for all individuals, but is especially important for women who may become pregnant. Evaluating the potential for adverse health effects associated with high folic acid intakes has been challenging because of the lack of systematic studies and other sources of evidence on this topic. In 1998, the Food and Nutrition Board of the Institute of Medicine set Dietary Reference Intakes that included the Recommended Dietary Allowances (RDAs) and tolerable upper intake levels (ULs)—the highest level of daily intake likely to pose no risk of adverse health effects to almost all of the population—for folic acid and other B vitamins. The folic acid UL (1000μg) was established with the paucity of data available to the committee at the time; i.e., limited but suggestive evidence that excessive folate intake may precipitate or exacerbate neuropathy in vitamin B12-deficient individuals. Since this 1998 publication that set the UL for folic acid, many publications have reported on health effects over a range of folic acid intakes. Some studies have raised concerns that high intake of folic acid may be associated with potential adverse health effects.

Folate is present in the diet through its natural occurrence in food, as a food additive, and as an ingredient in dietary supplements. Naturally occurring folate is unlikely to be associated with potential adverse effects because it has lower bioavailability than folic acid and its consumption is also limited by the bulk and caloric content of foods. Therefore, the primary substance of interest for considering the safety of high intake is folic acid, the form of folate commonly added to foods and dietary supplements.

Information gathered through this RFI will be used in prioritizing topics for the state of the science workshop. The date and location of the workshop have not yet been determined, but when set, will be announced in the **Federal Register**, the NIH Guide, and on the OHAT project Web site (*http://ntp.niehs.nih.gov/go/38144*). The overarching goals of this workshop are to identify research needs and inform the development of a research agenda for evaluating the safe use of high intakes of folic acid. The workshop will bring together experts from multiple disciplines including, but not limited to, epidemiology, nutrition, medicine, and toxicology.

Request for Comments: The NTP and the ODS invite comments on an approach document, ''Identifying Research Needs for Assessing Safe Use of High Intakes of Folic Acid,'' for review of the pertinent literature, which is available at *http://ntp.niehs.nih.gov/go/38143*. They also request information on issues related to evaluating potential adverse health effects of high intakes of folic acid. The RFI Web site contains specific questions for the following topics:

• Health effects of most concern for high folate intake
• Assessments of folic acid intake and folate levels that are relevant and validated for high exposure
• Critical co-factors for the evaluation of potential health impacts of folic acid
• Experts in the field who should be considered for inclusion in the workshop

Responses are invited from all interested parties, such as the nutrition research community, health professionals, educators, policy makers, industry, and the public. Responses to this RFI are voluntary. The comments collected will be analyzed and considered in planning and development of future initiatives. We do not intend to publish a summary of responses received or any other information provided, except very broad characterizations, such as the number of responses received. Despite this, proprietary, classified, or confidential information should not be included in your response. This RFI is for planning purposes only and is not a solicitation for applications or an obligation on the part of the U.S. Government to provide support for any ideas identified in response to it. Please note that the U.S. Government will not pay for the preparation of any comment submitted or for its use of that comment.

Background Information on NTP and ODS: The NTP is an interagency program, established in 1978 (43 FR 53060) and headquartered at the NIEHS, whose mission is to evaluate agents of public health concern by developing and applying tools of modern toxicology and molecular biology. The NTP carries out literature analysis activities in the Office of Health Assessment and Translation and the Office of the Reports on Carcinogens within the Division of the NTP. The NTP also designs and conducts laboratory studies and testing programs and analyzes its findings to assess potential hazards to human health from exposure to environmental substances, including dietary supplements (*see http://ntp.niehs.nih.gov/*).

The mission of the ODS is to strengthen knowledge and understanding of dietary supplements by evaluating scientific information, stimulating and supporting research, disseminating research results, and educating the public to foster an enhanced quality of life and health for the U.S. population. The purpose and responsibilities of the ODS are to explore more fully the potential role of dietary supplements as a significant part of the efforts of the United States to improve health care; to promote scientific study of the benefits of dietary supplements in maintaining health and preventing chronic disease and other health-related conditions; to conduct and coordinate scientific research within NIH relating to dietary supplements; to collect and compile the results of scientific research relating to dietary supplements, including scientific data from foreign sources; and to serve as the principal advisor to the Secretary of the Department of Health and Human Services and the Assistant Secretary for Health and to provide advice on issues relating to dietary supplements to the Director of NIH, the Director of the Centers for Disease Control and Prevention, and the Commissioner of the Food and Drug Administration (*see http://ods.od.nih.gov/*). The Dietary Supplement Health and Education Act of 1994 (Public Law 103–417, DSHEA), authorized the establishment of the ODS at the NIH in 1995.

Dated: April 1, 2013.

John R. Bucher,

Associate Director, National Toxicology Program.

[FR Doc. 2013–07901 Filed 4–4–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[Docket No. DHS–2013–0026]

Privacy Act of 1974; Department of Homeland Security/U.S. Citizenship and Immigration Services-015 Electronic Immigration System-2 Account and Case Management System of Records

AGENCY: Privacy Office, Department of Homeland Security.

ACTION: Notice of Privacy Act System of Records.

SUMMARY: In accordance with the Privacy Act of 1974, the Department of Homeland Security proposes to update and reissue a current Department of Homeland Security system of records titled, ''Department of Homeland Security/U.S. Citizenship and Immigration Services-015 Electronic Immigration System-2 Account and Case Management System of Records.'' This system of records allows the Department of Homeland Security/U.S. Citizenship and Immigration Services to: collect and maintain records on an individual after that individual submits a benefit request and/or creates or updates a U.S. Citizenship and Immigration Services Electronic Immigration System account; gather any missing information; manage workflow; assist U.S. Citizenship and Immigration Services in making a benefit determination; and provide a repository of data to assist with the efficient processing of future benefit requests. U.S. Citizenship and Immigration Services Electronic Immigration System-2 Account and Case Management will also be used to process and track all actions related to a particular case, including scheduling of biometrics appointments and interviews, requests for evidence or additional information, and issuing decision notices and/or proofs of benefit. This notice updates this system of records to (1) include additions to the categories of individuals and categories of records, (2) clarify routine uses ''A,'' ''H,'' ''L,'' and ''M,'' (3) delete routine use ''S,'' and (4) reflect a reduced retention period for attorney and accredited representative accounts. Additionally, this notice includes non-substantive changes to simplify the formatting and text of the previously published notices. The exemptions for the existing system of records notice will continue to be applicable for this system of records notice. Additionally, this system will continue to be included in the Department of Homeland Security's inventory of record systems.

DATES AND COMMENTS: Submit comments on or before May 6, 2013. In particular, DHS requests comments concerning the application of the exemptions to the newly added categories of individuals and category of records. This updated system will be effective May 6, 2013.

ADDRESSES: You may submit comments, identified by docket number DHS–2013–0026 by one of the following methods:

• *Federal e-Rulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.
• *Fax:* 202–343–4010.
• *Mail:* Jonathan R. Cantor, Acting Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, please visit *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For general questions, please contact:

Donald K. Hawkins, (202) 272–8000, Privacy Officer, U.S. Citizenship and Immigration Services, 20 Massachusetts Avenue NW., Washington, DC 20529. For privacy questions, please contact: Jonathan R. Cantor, (202) 343–1717, Acting Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the Privacy Act of 1974, 5 U.S.C. 552a, the Department of Homeland Security (DHS) U.S. Citizenship and Immigration Services (USCIS) proposes to update and reissue a current DHS system of records titled, ''DHS/USCIS–015 Electronic Immigration System-2 Account and Case Management System of Records'' (November 15, 2011, 76 FR 70739).

USCIS is the component of DHS that oversees immigration benefit requests from foreign nationals seeking to enter, be admitted to, or currently residing in the United States. USCIS transformed its operations and created a new electronic environment known as USCIS Electronic Immigration System (USCIS ELIS), which allows individuals requesting USCIS benefits to create immigration accounts online and submit certain benefit requests.

Applicants and petitioners (Applicants); co-applicants, beneficiaries, derivatives, dependents, or other persons on whose behalf a benefit request is made or whose immigration status may be derived because of a relationship to an Applicant (Co-Applicants); and/or their attorneys and representatives recognized by USCIS and/or accredited by the Board of Immigration Appeals (Representatives) may create individualized online accounts. These online accounts help Applicants and their Representatives file for benefits, track the status of open benefit requests, schedule appointments, change their addresses and contact information, and receive notices and notifications regarding their cases. Through USCIS ELIS, individuals also may submit evidence electronically.

USCIS ELIS uses information provided on initial and subsequent benefit requests and subsequent information collections through the USCIS ELIS Account and Case Management process to create or update USCIS ELIS accounts; collect any missing information; manage workflow; assist USCIS adjudicators as they make benefit determinations; and provide a repository of data to assist with future benefit requests. In addition, USCIS ELIS processes and tracks all actions related to the case, including scheduling biometrics appointments and interviews, requesting evidence or additional information, and issuing decision notices and/or proofs of benefit.

This system of records is being updated and reissued to (1) include additions to the categories of individuals and categories of records, (2) clarify routine uses ''A,'' ''H,'' ''L,'' and ''M,'' (3) delete routine use ''S,'' and (4) reflect a reduced retention period for attorney and accredited representative accounts.

Categories of individuals are being updated to include Interpreters and Sponsors to better reflect the ways USCIS ELIS captures data and to include data to be collected as additional benefit types are incorporated into USCIS ELIS. Categories of records for Applicants and Co-Applicants are being updated to include:

- U.S. County;
- Fax Numbers;
- Notices and Communications;
- Other Immigration-Related Identification Numbers including:
  - Immigration and Customs Enforcement (ICE) Student and Exchange Visitor Number; and
  - USCIS E-Verify Company Identification Number;
- Tax Records;
- Travel History;
- Professional Accreditation Information; and
- Relationships to Sponsors, Representatives, Preparers, Co-Applicants, and other Applicants.

Categories of records for Representatives are being updated to include Signature.

Categories of Records for Interpreters are being added and include:

- Name;
- Organization;
- Physical and Mailing Addresses;
- Email Address;
- Phone and Fax Numbers;
- Relationship to Applicant;
- Whether Interpreters are Paid/Not Paid;
- Business State ID Number; and
- Signature.

Categories of records for Preparers are being updated to include:

- Whether Preparers or Interpreters are Paid/Not Paid;
- Business State ID Number; and
- Signature.

Categories of records about Sponsors are being added and include:

- Full Name;
- Gender;
- Physical and Mailing Addresses;
- Phone and Fax Numbers;
- Country of Domicile;
- Date of Birth;
- Place of Birth;
- Citizenship Information;
- Social Security Number (SSN);
- Alien Registration Number (A-Number);
- Employment Information;
- Financial Information;
- Position and Relationship to an Organization;
- Family Relationships and Relationship Practices; and
- Signature.

This updated notice clarifies the following routine uses. Routine use ''A'' has been updated to correct a grammatical error. Routine use ''H'' has been updated to clarify under which circumstances USCIS would release records to clerks and judges of courts exercising naturalization jurisdiction. Routine use ''L'' has been updated to read ''requests'' instead of ''petitions or applications.'' Routine use ''M'' has been updated to correct a typographical error. One routine use listed in the previous notice is omitted in this update. Previous routine use ''S,'' which provided disclosure to certain members of Congress, was deleted because it was duplicative to existing authorization to disclose records under 5 U.S.C. 552a(b)(9). Finally, this updated notice includes a note explaining that confidentiality laws and policies may limit the sharing of some information that may otherwise be shared under a valid routine use.

This updated notice also presents a different retention period for information about attorneys and accredited representatives. USCIS will propose to the National Archive and Records Administration that USCIS ELIS accounts for attorneys and accredited representatives be retained for 7 years, 6 months.

Information in this system comes from the USCIS Electronic Immigration System-1 (USCIS ELIS Temporary Accounts and Draft Benefit Requests), which stores draft account and case information from Applicants and their Representatives. Once that draft information is signed and formally submitted with payment to USCIS, it becomes part of this USCIS Electronic Immigration System-2 (USCIS ELIS Account and Case Management). Results from USCIS Electronic Immigration System-3 Automated Background Functions (USCIS ELIS Automated Background Functions) will also be stored in the individual's USCIS ELIS account and/or case. This includes information from other USCIS, DHS, and federal government systems to confirm identity, determine eligibility,

and perform background checks. This USCIS ELIS Account and Case Management system may store information from other DHS systems including: DHS/USCIS/ICE/CBP (U.S. Customs and Border Patrol)-001 Alien File, Index, and National File Tracking System of Records; DHS/USCIS–006 Fraud Detection and National Security Data System (FDNS–DS); DHS/USCIS–007 Benefits Information System (BIS); DHS/USCIS–010 Asylum Information and Pre-Screening; DHS/USCIS–014 Electronic Immigration System-1 Temporary Accounts and Draft Benefit Requests System of Records (USCIS ELIS–1); DHS/USCIS–016 Electronic Immigration System-3 Automated Background Functions System of Records (USCIS ELIS–3); DHS/CBP–011—U.S. Customs and Border Protection TECS; DHS/ICE–001 Student and Exchange Visitor Information System (SEVIS); DHS/ICE–011 Immigration Enforcement Operational Records System (ENFORCE); DHS/USVISIT (United States Visitor and Immigrant Status Indicator Technology)-001 Arrival and Departure Information System (ADIS); and DHS/USVISIT–004 DHS Automated Biometric Identification System (IDENT).

Furthermore, USCIS ELIS Account and Case Management may store information from systems outside of DHS, including: Overseas Citizens Services Records, STATE–05; Passport Records, STATE–26; Visa Records, STATE–39; JUSTICE/EOIR (Department of Justice, Executive Office for Immigration Review)-001 Records and Management Information System; JUSTICE/FBI (Department of Justice, Federal Bureau of Investigations)-002 FBI Central Records System; JUSTICE/FBI–009 Fingerprint Identification Records System (FIRS); and TREASURY/FMS (Department of Treasury, Financial Management Service)-017 Collections Records.

USCIS ensures that all USCIS ELIS employees receive training and agree to USCIS-wide system rules of behavior before being granted access. USCIS provides security awareness training to all information system users (including managers, senior executives, and contractors) as part of initial training for new users, when required by system changes, and annually thereafter. DHS personnel and contractors with significant security responsibilities (e.g., adjudicators and system administrators) initially receive specialized training on USCIS ELIS functionality that is specific to their security responsibilities prior to being granted access to DHS systems. Thereafter, DHS personnel and contractors must complete annual refresher training.

USCIS collects, uses, and maintains account and case management information pursuant to Sections 103 and 290 of the INA (8 U.S.C. 1103 and 1360), and the regulations issued pursuant thereto; and Section 451 of the Homeland Security Act of 2002 (Pub. L. 107–296).

Consistent with DHS's information sharing mission, information stored in the DHS/USCIS–015 Electronic Immigration Services-2 Account and Case Management, may be shared with other DHS components that have a need to know the information to carry out their national security, law enforcement, immigration, intelligence, or other homeland security functions. In addition, information may be shared with appropriate federal, state, local, tribal, territorial, foreign, or international government agencies consistent with the routine uses set forth in this system of records notice.

Additionally, DHS has issued a Final Rule, 76 FR 70638, to exempt this system of records from certain provisions of the Privacy Act pursuant to 5 U.S.C. 552a(k)(2). The exemptions for the existing system of records notice will continue to be applicable for this system of records notice. DHS is requesting comments concerning the application of the exemptions to the newly added categories of individuals and category of records.

II. Privacy Act

The Privacy Act embodies fair information practice principles in a statutory framework governing the means by which federal government agencies collect, maintain, use, and disseminate individuals' records. The Privacy Act applies to information that is maintained in a ''system of records.'' A ''system of records'' is a group of any records under the control of an agency from which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to the individual. In the Privacy Act, an individual is defined to encompass U.S. citizens and lawful permanent residents. As a matter of policy, DHS extends administrative Privacy Act protections to all individuals when systems of records maintain information on U.S. citizens, lawful permanent residents, and visitors.

Below is the description of the DHS/USCIS-015 Electronic Immigration System-2 Account and Case Management System of Records.

In accordance with 5 U.S.C. 552a(r), DHS has provided a report of this system of records to the Office of Management and Budget (OMB) and to Congress.

SYSTEM OF RECORDS

DHS/USCIS–015

SYSTEM NAME:

DHS/USCIS–015 Electronic Immigration System-2 Account and Case Management System of Records

SECURITY CLASSIFICATION:

Unclassified, sensitive, for official use only, and/or law enforcement sensitive.

SYSTEM LOCATION:

Records are maintained in USCIS ELIS and associated electronic and paper files located at USCIS Headquarters in Washington, DC and in USCIS service centers and field offices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

USCIS ELIS Account and Case Management stores and/or uses information about individuals who request and/or receive immigration benefits under the INA. These individuals include: applicants and petitioners (Applicants); co-applicants, beneficiaries, derivatives, dependents, or other persons on whose behalf a benefit request is made or whose immigration status may be derived because of a relationship to an Applicant (Co-Applicants); members of organizations petitioning for benefits under the INA on behalf of, or contributing to, the financial support of an Applicant or Co-Applicant (Sponsors); attorneys and representatives recognized by USCIS and/or accredited by the Board of Immigration Appeals (Representatives); Interpreters; and individuals who assist in the preparation of the benefit request (Preparers).

CATEGORIES OF RECORDS IN THE SYSTEM:

Account information about Applicants and Co-Applicants may include:

- USCIS ELIS Account Number;
- A-Number(s);
- Family Name;
- Given Name;
- Middle Name;
- Alias(es);
- Physical and Mailing Address(es):
  - Address
  - Unit Number
  - City
  - State
  - ZIP Code
  - Postal Code
  - U.S. County
  - Province
  - Country

- Date of Birth;
- Deceased Date;
- Nationality;
- Country of Citizenship;
- City of Birth;
- State of Birth;
- Province of Birth;
- Country of Birth;
- Gender;
- Marital Status;
- Military Status;
- Preferred Contact Method;
- Phone and Fax Numbers;
- Phone Extension;
- Email Address;
- Password;
- Challenge Questions and Answers;
- Immigration Status;
- Government-issued Identification (e.g., passport, driver's license):
  - Document Type
  - Issuing Organization
  - Document Number
  - Expiration Date
- Benefit Requested;
- Notices and Communications, including:
  - Receipt Notices
  - Requests for Evidence
  - Notices of Intent to Deny
  - Account Update Notifications
  - Proofs of Benefit
  - o Statements of Findings
- Signature (electronic or scanned physical signature);
- Pay.gov Payment Tracking Number;
- IP Address and Browser Information as part of the E-Signature;
- USCIS ELIS Case Submission Confirmation Number.

Benefit-specific eligibility information about Applicants and Co-Applicants may include:

- Other Immigration-Related Identification Numbers (e.g., DOS-Issued Personal Identification Number, ICE Student and Exchange Visitor Number, USCIS E-Verify Company Identification Number);
- Arrival/Departure Information;
- Immigration History (e.g., citizenship/naturalization certificate number, removals, explanations);
- Family Relationships (e.g., parent, spouse, sibling, child, other dependents) and Relationship Practices (e.g., polygamy, custody, guardianship);
- USCIS Receipt/Case Number;
- Personal Background Information (e.g., involvement with national security threats, criminal offenses, Communist party, torture, genocide, killing, injuring, forced sexual contact, limiting or denying others religious beliefs, service in military or other armed groups, work in penal or detention systems, weapons distribution, combat training);
- Health Information (e.g., vaccinations, referrals, communicable diseases, physical or mental disorders, prostitution, drug or alcohol abuse);
- Travel History;
- Education History;
- Work History;
- Professional Accreditation Information;
- Financial Information (e.g., income, expenses, scholarships, savings, assets, property, financial support, supporter information, life insurance, debts, encumbrances, tax records);
- SSN, if applicable;
- Supporting documentation as necessary (e.g., birth, marriage, and/or divorce certificates, appeals or motions to reopen or reconsider decisions, explanatory statements, and unsolicited information submitted voluntarily by the Applicants or Co-Applicants in support of a benefit request);
- Physical Description (e.g., height, weight, eye color, hair color, identifying marks like tattoos or birthmarks);
- Fingerprint(s);
- Photographs;
- FBI Identification Number;
- Fingerprint Identification Number;
- Criminal Records;
- Criminal and National Security Background Check Information;
- Relationships to Sponsors, Representatives, Preparers, Co-Applicants, and other Applicants.

Information about Sponsors may include:

- Full Name;
- Gender;
- Physical and Mailing Addresses:
  - Address
  - Unit Number
  - City
  - State
  - ZIP Code
  - Postal Code
  - U.S. County
  - Province
  - Country
- Phone and Fax Numbers;
- Country of Domicile;
- Date of Birth;
- City of Birth;
- State of Birth;
- Province of Birth;
- Country of Birth;
- Citizenship Information;
- SSN;
- A-Number;
- Employment Information;
- Financial Information (e.g., income, expenses, scholarships, savings, assets, property, financial support, supporter information, life insurance, debts, encumbrances, tax records);
- Position and Relationship to an Organization (e.g., manager of a company seeking formal recognition by USCIS);
- Family Relationships (e.g., parent, spouse, sibling, child, other dependents) and Relationship Practices (e.g., polygamy, custody, guardianship);
- Signature (electronic or scanned physical signature).

Information about Representatives may include:

- Name;
- Law Firm/Recognized Organization;
- Physical and Mailing Addresses:
  - Address
  - Unit Number
  - City
  - State
  - ZIP Code
  - Postal Code
  - U.S. County
  - Province
  - Country
- Phone and Fax Numbers;
- Email Address;
- Attorney Bar Card Number or Equivalent;
- Bar Membership;
- Accreditation Date;
- Board of Immigration Appeals Representative Accreditation;
- Expiration Date;
- Law Practice Restriction Explanation;
- Signature (electronic or scanned physical signature);

Information about Preparers and Interpreters may include:

- Full Name;
- Organization;
- Business State ID Number;
- Physical and Mailing Addresses:
  - Address
  - Unit Number
  - City
  - State
  - ZIP Code
  - Postal Code
  - U.S. County
  - Province
  - Country
- Email Address;
- Phone and Fax Numbers;
- Paid/Not Paid (i.e., whether the Preparer or Interpreter was paid for assisting the Applicant or Sponsor in completing or submitting the benefit request);
- Relationship to Applicant;
- Signature (electronic or scanned physical signature).

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Authority for maintaining this system is in Sections 103 and 290 of the INA, as amended (8 U.S.C. 1103 and 1360), and the regulations issued pursuant thereto; and Section 451 of the Homeland Security Act of 2002 (Pub. L. 107–296).

PURPOSE(S):

The purpose of this system is to manage USCIS ELIS on-line applicant,

representative, and organizational accounts; gather information related to a benefit request; manage workflow; generate reports; assist USCIS adjudicators in making a benefit determination; and provide a repository of data to assist with future benefit requests. In addition, the USCIS ELIS Account and Case Management process will be used to process and track all actions related to the case, including scheduling of biometrics appointments and interviews, requesting evidence or additional information, and issuing decision notices and/or proofs of benefit.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Note: Even when a valid routine use permits disclosure of information from this system of records to a third party, in some cases such disclosure may not be permissible because of confidentiality laws and policies that limit the sharing of information about the application for or award of certain immigration benefits. For example, information in this system of records contained in or pertaining to applications for asylum or refugee protection, information relating to persons who have pending or approved petitions for protection under the Violence Against Women Act, Seasonal Agricultural Worker or Legalization claims, the Temporary Protected Status of an individual, and information relating to S, T, or U nonimmigrant visas should not be disclosed pursuant to a routine use unless disclosure is otherwise permissible under the confidentiality statutes, regulations, or policies applicable to that information. These confidentiality provisions do not prevent DHS from disclosing information to the U.S. Department of Justice (DOJ) and U.S. Attorneys' Offices as part of an ongoing criminal or civil investigation.

In addition to those disclosures generally permitted under 5 U.S.C. § 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed outside DHS as a routine use pursuant to 5 U.S.C. § 552a(b)(3) as follows:

A. To DOJ, including U.S. Attorneys' Offices, or other federal agencies conducting litigation or in proceedings before any court, adjudicative or administrative body, when it is relevant or necessary to the litigation and one of the following is a party to the litigation or has an interest in such litigation:

1. DHS or any component thereof;

2. Any employee or former employee of DHS in his/her official capacity;

3. Any employee or former employee of DHS in his/her individual capacity when DOJ or DHS has agreed to represent the employee; or

4. The United States or any agency thereof.

B. To a congressional office from the record of an individual in response to an inquiry from that congressional office made at the request of the individual to whom the record pertains.

C. To the National Archives and Records Administration (NARA) or General Services Administration pursuant to records management inspections being conducted under the authority of 44 U.S.C. 2904 and 2906.

D. To an agency or organization for the purpose of performing audit or oversight operations as authorized by law, but only such information as is necessary and relevant to such audit or oversight function.

E. To appropriate agencies, entities, and persons when:

1. DHS suspects or has confirmed that the security or confidentiality of information in the system of records has been compromised;

2. DHS has determined that as a result of the suspected or confirmed compromise, there is a risk of identity theft or fraud, harm to economic or property interests, harm to an individual, or harm to the security or integrity of this system or other systems or programs (whether maintained by DHS or another agency or entity) that rely upon the compromised information; and

3. The disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with DHS's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

F. To contractors and their agents, grantees, experts, consultants, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for DHS, when necessary to accomplish an agency function related to this system of records. Individuals provided information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as are applicable to DHS officers and employees.

G. To an appropriate federal, state, tribal, local, international, or foreign law enforcement agency or other appropriate authority charged with investigating or prosecuting a violation or enforcing or implementing a law, rule, regulation, or order, where a record, either on its face or in conjunction with other information, indicates a violation or potential violation of law, which includes criminal, civil, or regulatory violations and such disclosure is proper and consistent with the official duties of the person making the disclosure.

H. To clerks and judges of courts exercising naturalization jurisdiction to review naturalization decisions, entertain requests for hearings, or consider the revocation of naturalization, and to enable those courts to determine whether a naturalization case should be remanded to DHS, whether an individual is eligible for naturalization, or if an individual previously granted naturalization should have naturalization revoked.

I. To courts, magistrates, administrative tribunals, opposing counsel, parties, and witnesses, in the course of immigration, civil, or criminal proceedings before a court or adjudicative body when:

1. DHS or any component thereof; or

2. Any employee of DHS in his or her official capacity; or

3. Any employee of DHS in his or her individual capacity when the agency has agreed to represent the employee; or

4. The United States, when DHS determines that litigation is likely to affect DHS or any of its components; is a party to litigation or has an interest in such litigation, and DHS determines that use of such records is relevant and necessary to the litigation, and that in each case, DHS determines that disclosure of the information to the recipient is compatible with the purpose for which it was collected.

J. To an attorney or representative (as defined in 8 CFR 1.1(j)) who is acting on behalf of an individual covered by this system of records in connection with any proceeding before USCIS, ICE, CBP, or DOJ EOIR.

K. To DOJ (including United States Attorneys' Offices) or other federal agencies conducting litigation or in proceedings before any court, adjudicative, or administrative body, when necessary to assist in the development of such agency's legal and/or policy position.

L. To DOS in the processing of requests for benefits under the INA, and all other immigration and nationality laws including treaties and reciprocal agreements; or when DOS requires information to consider and/or provide an informed response to a request for information from a foreign, international, or intergovernmental agency, authority, or organization about an alien or an enforcement operation with transnational implications.

M. To an appropriate federal, state, local, tribal, territorial, or foreign government agency or organization, as well as to other individuals and organizations during the course of an

investigation by DHS or the processing of a matter under DHS's jurisdiction, or during a proceeding within the purview of the immigration and nationality laws, when DHS deems that such disclosure is necessary to carry out its functions and statutory mandates or to elicit information required by DHS to carry out its functions and statutory mandates.

N. To an appropriate federal, state, local, tribal, territorial, or foreign government agency or organization, or international organization, lawfully engaged in collecting law enforcement intelligence, whether civil or criminal, or charged with investigating, prosecuting, enforcing or implementing civil or criminal laws, related rules, regulations or orders, to enable these entities to carry out their law enforcement responsibilities, including the collection of law enforcement intelligence, and the disclosure is appropriate to the proper performance of the official duties of the person receiving the information.

O. To an appropriate federal, state, local, tribal, territorial, or foreign government agency or organization, or international organization, if the information is relevant and necessary to a requesting agency's decision concerning the hiring or retention of an individual, or issuance of a security clearance, license, contract, grant, or other benefit, or if the information is relevant and necessary to a DHS decision concerning 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, grant, or other benefit.

P. To an individual's current employer to the extent necessary to determine employment eligibility or to a prospective employer or government agency to verify an individual is eligible for a government-issued credential that is a condition of employment.

Q. To a former employee of DHS, in accordance with applicable regulations, for purposes of: responding to an official inquiry by a federal, state, or local government entity or professional licensing authority; or facilitating communications with a former employee that may be necessary for personnel-related or other official purposes when the Department requires information or consultation assistance from the former employee regarding a matter within that person's former area of responsibility.

R. To OMB in connection with the review of private relief legislation as set forth in OMB Circular No. A–19 at any stage of the legislative coordination and clearance process as set forth in the Circular.

S. To a federal, state, tribal, or local government agency and/or to domestic courts to assist such agencies in collecting the repayment of loans, or fraudulently or erroneously secured benefits, grants, or other debts owed to them or to the U.S. Government, or to obtain information that may assist DHS in collecting debts owed to the U.S. Government.

T. To an individual or entity seeking to post or arrange, or who has already posted or arranged, an immigration bond for an alien to aid the individual or entity in (1) identifying the location of the alien, or (2) posting the bond, obtaining payments related to the bond, or conducting other administrative or financial management activities related to the bond.

U. To a coroner for purposes of affirmatively identifying a deceased individual (whether or not such individual is deceased as a result of a crime).

V. Consistent with the requirements of the INA, to the Department of Health and Human Services (HHS), the Centers for Disease Control and Prevention, or to any state or local health authorities, to:

1. Provide proper medical oversight of DHS-designated civil surgeons who perform medical examinations of both arriving aliens and of those requesting status as lawful permanent residents; and

2. Ensure that all health issues potentially affecting public health and safety in the United States are being or have been adequately addressed.

W. To a federal, state, local, tribal, or territorial government agency seeking to verify or ascertain the citizenship or immigration status of any individual within the jurisdiction of the agency for any purpose authorized by law.

X. To the Social Security Administration (SSA) for the purpose of issuing a SSN and Social Security card to an alien who has made a request for a SSN as part of the immigration process and in accordance with any related agreements in effect between the SSA, DHS, and DOS entered into pursuant to 20 CFR §§ 422.103(b)(3); 422.103(c); and 422.106(a), or other relevant laws and regulations.

Y. To federal and foreign government intelligence or counterterrorism agencies or components where DHS becomes aware of an indication of a threat or potential threat to national or international security, or where such use is to conduct national intelligence and security investigations or assist in anti-terrorism efforts.

Z. To third parties to facilitate placement or release of an individual (e.g., at a group home, homeless shelter) who has been or is about to be released from DHS custody but only such information that is relevant and necessary to arrange housing or continuing medical care for the individual.

AA. To foreign governments for the purpose of coordinating and conducting the removal of individuals to other nations under the INA; and to international, foreign, and intergovernmental agencies, authorities, and organizations in accordance with law and formal or informal international arrangements.

BB. To a federal, state, local, territorial, tribal, international, or foreign criminal, civil, or regulatory law enforcement authority when the information is necessary for collaboration, coordination, and de-confliction of investigative matters, prosecutions, and/or other law enforcement actions to avoid duplicative or disruptive efforts and to ensure the safety of law enforcement officers who may be working on related law enforcement matters.

CC. To the DOJ Federal Bureau of Prisons and other federal, state, local, territorial, tribal, and foreign law enforcement or custodial agencies for the purpose of placing an immigration detainer on an individual in that agency's custody, or to facilitate the transfer of custody of an individual from DHS to the other agency. This will include the transfer of information about unaccompanied minor children to HHS to facilitate the custodial transfer of such children from DHS to HHS.

DD. To federal, state, local, tribal, territorial, or foreign governmental or quasi-governmental agencies or courts to confirm the location, custodial status, removal, or voluntary departure of an alien from the United States, in order to facilitate the recipients' exercise of responsibilities pertaining to the custody, care, or legal rights (including issuance of a U.S. passport) of the removed individual's minor children, or the adjudication or collection of child support payments or other debts owed by the removed individual.

EE. To federal, state, tribal, territorial, local, international, or foreign government agency or entity for the purpose of consulting with that agency or entity:

1. To assist in making a determination regarding redress for an individual in connection with the operations of a DHS component or program;

2. For the purpose of verifying the identity of an individual seeking redress

in connection with the operations of a DHS component or program; or

3. For the purpose of verifying the accuracy of information submitted by an individual who has requested such redress on behalf of another individual.

FF. To the Department of Treasury to process and resolve payment issues.

GG. To the news media and the public, with the approval of the Chief Privacy Officer in consultation with counsel, when there exists a legitimate public interest in the disclosure of the information or when disclosure is necessary to preserve confidence in the integrity of DHS or is necessary to demonstrate the accountability of DHS's officers, employees, or individuals covered by the system, except to the extent it is determined that release of the specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

None.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records in this system are stored electronically or on paper in secure facilities in a locked drawer behind a locked door. The records may be stored on magnetic disc, tape, and/or digital media.

RETRIEVABILITY:

Records may be retrieved by any of the data elements listed above or a combination thereof.

SAFEGUARDS:

Records in this system are safeguarded in accordance with applicable rules and policies, including all applicable DHS automated systems security and access policies. Strict controls have been imposed to minimize the risk of compromising the information that is being stored. Access to the computer system containing the records in this system is limited to those individuals who have a need to know the information for the performance of their official duties and who have appropriate clearances or permissions.

RETENTION AND DISPOSAL:

USCIS is currently working with NARA to establish and publish the proposed USCIS ELIS records retention schedules. USCIS currently plans to retain all account information and supporting evidence for 100 years after the account holder's date of birth, or 15 years from last action, whichever is later. Permanent accounts (e.g., for applicants who currently have A-files) and related case snapshots and supporting evidence are permanent and will be transferred to the custody of NARA 100 years after the individual's date of birth. Non-immigrant case information and supporting evidence will be stored for 15 years from last action. Representative accounts will be stored for 7 years, 6 months from last action. U.S. citizen accounts and cases will be archived internally after five years. All accounts and cases will be put in an inactive status 15 years after last action.

Records that are linked to national security, law enforcement, or fraud investigations or cases, will remain accessible for the life of the related activity, to the extent retention for such purposes exceeds the normal retention period for such data in USCIS ELIS. USCIS is reviewing its needs for the information as it transitions to a fully electronic environment and may amend its retention plans and schedules as needed.

USCIS proposes that, in compliance with NARA General Records Schedule 24, section 6, ''User Identification, Profiles, Authorizations, and Password Files,'' internal USCIS personnel accounts will be destroyed or deleted six years after the account is terminated, or when no longer needed for investigative or security purposes, whichever is later.

SYSTEM MANAGER AND ADDRESS:

The DHS system manager is the Chief, Office of Transformation Coordination, U.S. Citizenship and Immigration Services, Department of Homeland Security, 633 3rd Street NW., Washington, DC 20529.

NOTIFICATION PROCEDURE:

Applicants may access and amend this information by logging into their USCIS ELIS account. Individuals seeking notification of and access to any record contained in this system of records, or seeking to contest its content, may submit a request in writing to the National Records Center (NRC) FOIA/PA Office, P.O. Box 648010, Lee's Summit, MO 64064–8010. NRC's contact information can be found at *http://www.dhs.gov/foia* under ''Contacts.'' If an individual believes that more than one component maintains Privacy Act records concerning him or her, the individual may submit the request to the Chief Privacy Officer and Chief Freedom of Information Act Officer, Department of Homeland Security, 245 Murray Drive SW., Building 410, STOP–0655, Washington, DC 20528.

When seeking records about yourself from this system of records or any other Departmental system of records, your request must conform with the Privacy Act regulations set forth in 6 CFR Part 5. You must first verify your identity, meaning you must provide your full name, current address, and date and place of birth. You must sign your request, and your signature must be either notarized or submitted under 28 U.S.C. 1746, a law that permits statements to be made under penalty of perjury as a substitute for notarization. While no specific form is required, you may obtain forms for this purpose from the Chief Privacy Officer and Chief Freedom of Information Act Officer, *http://www.dhs.gov/foia* or 1–866–431–0486. In addition, you should:

- Explain why you believe the Department would have information on you;
- Identify which component(s) of the Department you believe may have the information about you;
- Specify when you believe the records would have been created; and
- Provide any other information that will help the FOIA staff determine which DHS component agency may have responsive records.

If your request is seeking records pertaining to another living individual, you must include a statement from that individual certifying his/her agreement for you to access his/her records.

Without the above information, the component(s) may not be able to conduct an effective search, and the request may be denied due to lack of specificity or lack of compliance with applicable regulations.

RECORD ACCESS PROCEDURES:

See ''Notification procedure'' above.

CONTESTING RECORD PROCEDURES:

See ''Notification procedure'' above.

RECORD SOURCE CATEGORIES:

Records are obtained from the Applicant, the primary Applicant for a Co-Applicant, Sponsor, his or her Representative, Preparer, or Interpreter. USCIS personnel may input information as they process a case, including information from commercial sources to verify whether an Applicant or Co-Applicant is eligible for the benefit requested. USCIS ELIS Account and Case Management will also store and use information from the following USCIS, DHS, and other federal agency systems of records:

- DHS/USCIS/ICE/CBP–001 Alien File, Index, and National File Tracking

System of Records, 76 FR 34233 (June 13, 2011);

- DHS/USCIS–007 Benefits Information System, 73 FR 56596 (September 29, 2008);
- DHS/USCIS–010 Asylum Information and Pre-Screening, 75 FR 409 (January 5, 2010);
- DHS/USCIS–006 Fraud Detection and National Security Records (FDNS) 77 FR 47411 (August 8, 2012);
- DHS/USCIS–014 Electronic Immigration System-1 Temporary Accounts and Draft Benefit Requests System of Records, 76 FR 70730 (November 15, 2011);
- DHS/USCIS–016 Electronic Immigration System-3 Automated Background Functions System of Records, 76 FR 70735 (November 15, 2011);
- DHS/CBP–011 U.S. Customs and Border Protection TECS, 73 FR 77778 (December 19, 2008);
- DHS/ICE–001 Student and Exchange Visitor Information System, 75 FR 412 (January 5, 2010);
- DHS/ICE–011 Immigration and Enforcement Operational Records System (ENFORCE), 75 FR 23274 (May 3, 2010);
- DHS/USVISIT–001 Arrival and Departure Information System (ADIS), 72 FR 47057 (August 22, 2007);
- DHS/USVISIT–004 DHS Automated Biometric Identification System (IDENT), 72 FR 31080 (June 5, 2007);
- Overseas Citizens Services Records, STATE–05, 73 FR 24343 (May 2, 2008);
- Passport Records, STATE–26, 76 FR 34966 (July 6, 2011);
- Visa Records, STATE–39, 77 FR 65245 (October 25, 2012);
- JUSTICE/EOIR–001 Records and Management Information System, 72 FR 3410 (January 25, 2007);
- JUSTICE/FBI–002 The FBI Central Records System, 72 FR 3410 (January 25, 2007);
- JUSTICE/FBI–009 Fingerprint Identification Records System (FIRS), 72 FR 3410 (January 25, 2007); and
- TREASURY/FMS–017 Collections Records, 74 FR 23006 (May 15, 2009).

EXEMPTIONS CLAIMED FOR THE SYSTEM:

The Secretary of Homeland Security has exempted this system from the following provisions of the Privacy Act pursuant to 5 U.S.C. 552a(k)(2): 5 U.S.C. 552a(c)(3); (d); (e)(1), (e)(4)(G), (e)(4)(H), (e)(4)(I); and (f). Additionally, many of the functions in this system require retrieving records from law enforcement systems. When a record received from another system has been exempted in that source system under 5 U.S.C. 552a(j)(2), DHS will claim the same exemptions for those records that are claimed for the original primary systems of records from which they originated and claims any additional exemptions set forth here.

Dated: March 22, 2013.

Jonathan R. Cantor,

Acting Chief Privacy Officer, Department of Homeland Security.

[FR Doc. 2013–07725 Filed 4–4–13; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[Docket No. DHS–2013–0025]

Privacy Act of 1974; Department of Homeland Security/U.S. Citizenship and Immigration Services-014 Electronic Immigration System-1 Temporary Accounts and Draft Benefit Requests System of Records

AGENCY: Privacy Office, Department of Homeland Security.

ACTION: Notice of Privacy Act System of Records.

SUMMARY: In accordance with the Privacy Act of 1974, the Department of Homeland Security proposes to update and reissue a current Department of Homeland Security system of records titled, ''Department of Homeland Security/U.S. Citizenship and Immigration Services-014 Electronic Immigration System-1 Temporary Accounts and Draft Benefit Requests System of Records.'' This system of records allows the Department of Homeland Security/U.S. Citizenship and Immigration Services to collect and maintain records on an individual as he or she creates a temporary electronic account and/or drafts a benefit request for submission through the U.S. Citizenship and Immigration Services Electronic Immigration System. This notice updates this system of records to (1) include additions to the categories of individuals and categories of records and (2) reflect an approved retention schedule for temporary accounts and draft benefit requests. Additionally, this notice includes non-substantive changes to simplify the formatting and text of the previously published notices. This updated system will be included in the Department of Homeland Security's inventory of record systems.

DATES AND COMMENTS: Submit comments on or before May 6, 2013. This updated system will be effective May 6, 2013.

ADDRESSES: You may submit comments, identified by docket number DHS–2013–0025 by one of the following methods:

- *Federal e-Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–343–4010.
- *Mail:* Jonathan R. Cantor, Acting Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, please visit *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For general questions, please contact: Donald K. Hawkins, (202) 272–8000, Privacy Officer, U.S. Citizenship and Immigration Services, 20 Massachusetts Avenue NW., Washington, DC 20529. For privacy questions, please contact: Jonathan R. Cantor, (202) 343–1717, Acting Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the Privacy Act of 1974, 5 U.S.C. 552a, the Department of Homeland Security (DHS) U.S. Citizenship and Immigration Services (USCIS) proposes to update and reissue a current DHS system of records titled, ''DHS/USCIS–014 Electronic Immigration System-1 Temporary Accounts and Draft Benefit Requests System of Records'' (November 15, 2011, 76 FR 70739).

USCIS is the component of DHS that oversees immigration benefit requests from foreign nationals seeking to enter, be admitted to, or currently residing in the United States. USCIS is transforming its operations by creating a new electronic environment known as USCIS Electronic Immigration System (USCIS ELIS), which allows individuals requesting USCIS benefits to create immigration accounts online and submit certain benefit requests. Applicants and petitioners (Applicants); co-applicants, beneficiaries, derivatives, dependents, or other persons on whose behalf a benefit request is made or whose immigration status may be derived because of a relationship to an Applicant (Co-Applicants); and their attorneys and representatives recognized by USCIS and/or accredited by the Board of Immigration Appeals

(Representatives) may create individualized online accounts.

This System of Records Notice (SORN) addresses temporary data in USCIS ELIS. Temporary data includes draft account data provided by first-time Applicants in USCIS ELIS and draft benefit request data from all Applicants and Representatives.

This system of records is being updated and reissued to (1) include additions to the categories of individuals and categories of records, and (2) reflect an approved retention schedule for temporary accounts and draft benefit requests.

This update includes additions to the categories of individuals and records. Categories of individuals are being updated to include Interpreters and Sponsors to better reflect the ways USCIS ELIS captures data and to include data collected as additional benefit types are incorporated into USCIS ELIS.

Categories of records for Applicants and Co-Applicants are being updated to include:

- Phone Extension;
- Preferred Contact Method;
- Deceased Date;
- Nationality;
- Province of Birth;
- Marital Status;
- Fax Numbers;
- Notices and Communications;
- Other Immigration-Related Identification Numbers including:
  - Immigration and Customs Enforcement (ICE) Student and Exchange Visitor Number; and
  - USCIS E-Verify Company Identification Number;
- Travel History;
- Professional Accreditation Information;
- Tax Records;
- Marriage Certificates;
- Divorce Certificates;
- Explanatory Statements;
- Unsolicited information submitted voluntarily in support of a benefit request;
- Physical Description;
- Relationships to Sponsors, Representatives, Preparers, Co-Applicants, and other Applicants; and
- Signature.

Categories of records for Representatives are being updated to include:

- Signature.

Categories of Records for Interpreters are being updated to include:

- Name;
- Organization;
- Physical and Mailing Addresses;
- Phone and Fax Numbers;
- Whether the Interpreter is Paid/Not Paid; and
- Relationship to Applicant.

Categories of records for Preparers and Interpreters are being updated to include:

- Email Address;
- Business State ID Number; and
- Signature.

Categories of records about Sponsors are being updated to include:

- Full Name;
- Gender;
- Physical and Mailing Addresses;
- Phone and Fax Numbers;
- Country of Domicile;
- Date of Birth;
- City of Birth;
- State of Birth;
- Province of Birth;
- Country of Birth;
- Citizenship Information;
- Social Security Number (SSN);
- Alien Registration Number (A-Number);
- Employment Information;
- Financial Information;
- Position and Relationship to an Organization;
- Family Relationships and Relationship Practices; and
- Signature.

This updated notice includes a retention schedule approved by National Archives and Records Administration (NARA) for temporary accounts and draft benefit requests. Temporary account and draft benefit request data will be deleted 30 days after an individual begins, but fails to complete, the account registration and/or benefit submission process.

Because USCIS ELIS collects this information before an Applicant or Representative submits a benefit request, USCIS does not have an official need-to-know the data in a draft benefit request. USCIS separates temporary account and draft benefit request data from permanent information in USCIS ELIS to prevent USCIS personnel, aside from USCIS ELIS System Administrators as part of their system maintenance duties, from viewing temporary data until the Applicant or Representative submits the benefit request.

When an Applicant creates a USCIS ELIS account, USCIS ELIS classifies that account as temporary until the Applicant submits a benefit request. If an Applicant does not begin drafting a benefit request within 30 days of opening the temporary account, USCIS ELIS deletes the temporary account. USCIS ELIS converts the account from temporary to permanent once an Applicant submits a benefit request in USCIS ELIS. USCIS ELIS processes permanent accounts in accordance with the Electronic Immigration System-2 Account and Case Management SORN and Electronic Immigration System-3 Automated Background Functions SORN.

Once an Applicant or Representative begins drafting a benefit request, he or she will have 30 days to submit it. If an Applicant with a temporary account does not submit a benefit request within 30 days of starting a draft benefit request, USCIS ELIS deletes the temporary account and all draft benefit request data. If the Applicant with a permanent account or the Representative does not submit the benefit request within 30 days, USCIS ELIS will delete the draft benefit request but retain the permanent accounts. When an Applicant or Representative formally submits a benefit request to USCIS, the information will be retained and used according to the Electronic Immigration System-2 Account and Case Management SORN and Electronic Immigration System-3 Automated Background Functions SORN.

USCIS ensures that all USCIS ELIS employees receive training and agree to USCIS-wide system rules of behavior before being granted access. USCIS provides security awareness training to all information system users (including managers, senior executives, and contractors) as part of initial training for new users, when required by system changes, and annually thereafter. DHS personnel and contractors with significant security responsibilities (e.g., adjudicators and system administrators) initially receive specialized training on USCIS ELIS functionality that is specific to their security responsibilities prior to being granted access to DHS systems. Thereafter, DHS personnel and contractors must complete annual refresher training.

USCIS collects, uses, and maintains temporary account and draft benefit request information pursuant to the Immigration and Nationality Act of 1952 (INA), Public Law No. 82–414, sections 101 and 103, as amended. This updated system will be effective May 6, 2013.

II. Privacy Act

The Privacy Act embodies fair information practice principles in a statutory framework governing the means by which federal government agencies collect, maintain, use, and disseminate individuals' records. The Privacy Act applies to information that is maintained in a ''system of records.'' A ''system of records'' is a group of any records under the control of an agency from which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to the

individual. In the Privacy Act, an individual is defined to encompass U.S. citizens and lawful permanent residents. As a matter of policy, DHS extends administrative Privacy Act protections to all individuals when systems of records maintain information on U.S. citizens, lawful permanent residents, and visitors.

Below is the description of the DHS/USCIS–014 Electronic Immigration System-1 Temporary Accounts and Draft Benefit Requests System of Records.

In accordance with 5 U.S.C. 552a(r), DHS has provided a report of this system of records to the Office of Management and Budget and to Congress.

SYSTEM OF RECORDS

DHS/USCIS–014

SYSTEM NAME:

DHS/USCIS–014 Electronic Immigration System-1 Temporary Accounts and Draft Benefit Requests System of Records

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Records are maintained at the USCIS Headquarters in Washington, DC and in USCIS service centers and field offices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

USCIS ELIS Temporary Accounts and Draft Benefit Requests stores and/or uses information about individuals who apply or petition for or receive benefits under the INA. These individuals include: Applicants and petitioners (Applicants); co-applicants, beneficiaries, derivatives, dependents, or other persons on whose behalf a benefit request is made or whose immigration status may be derived because of a relationship to an Applicant (Co-Applicants); members of organizations petitioning for benefits under the INA on behalf of, or contributing to, the financial support of an Applicant or Co-Applicant (Sponsors); attorneys and representatives recognized by USCIS and/or accredited by the Board of Immigration Appeals (Representatives); Interpreters; and individuals who assist in the preparation of the benefit request (Preparers).

CATEGORIES OF RECORDS IN THE SYSTEM:

Temporary account registration information about Applicants and Co-Applicants may include:

- Email address;
- Password;
- Challenge questions and answers;
- Telephone Number;
- Phone Extension;
- Preferred Contact Method;

Temporary account information about Applicants and Co-Applicants may include:

- A-Number;
- Family Name;
- Given Name;
- Middle Name;
- Alias(es);
- Physical and mailing addresses:
  - Address;
  - Unit Number;
  - City;
  - State;
  - ZIP Code;
  - Postal Code;
  - U.S. County;
  - Province;
  - Country;
- Date of Birth;
- Deceased Date;
- Nationality;
- Country of Citizenship;
- City of Birth;
- State of Birth;
- Province of Birth;
- Country of Birth;
- Gender;
- Marital Status;
- Military Status;
- Fax Numbers;
- Immigration Status;
- Government-issued Identification (e.g. passport, driver's license):
  - Document Type;
  - Issuing Organization;
  - Document Number;
  - Expiration Date;
- Benefit Requested;
- Notices and Communications, including:
  - Account Update Notifications;
- IP Address and Browser Information as part of the E-Signature.

Benefit-specific eligibility information about Applicants and Co-Applicants may include:

- Other Immigration-Related Identification Numbers (e.g., U.S. Department of State-Issued Personal Identification Number, ICE Student and Exchange Visitor Number, USCIS E-Verify Company Identification Number);
- Arrival/Departure Information;
- Family Relationships (e.g., parent, spouse, sibling, child, other dependents) and Relationship Practices (e.g., polygamy, custody, guardianship);
- USCIS Receipt/Case Number;
- Personal Background Information (e.g., involvement with national security threats, criminal offenses, Communist party, torture, genocide, killing, injuring, forced sexual contact, limiting or denying others religious beliefs; service in military or other armed groups; work in penal or detention systems, weapons distribution, combat training);
- Health Information (e.g., vaccinations, referrals, communicable disease, physical or mental disorder, prostitution, drug or alcohol abuse);
- Travel History;
- Education History;
- Work History;
- Professional Accreditation Information;
- Financial Information (income, expenses, scholarships, savings, assets, property, financial support, supporter information, life insurance, debts, encumbrances, tax records);
- SSN;
- Supporting documentation as necessary (e.g., birth, marriage, and/or divorce certificates, appeals or motions to reopen or reconsider decisions, explanatory statements, and unsolicited information submitted voluntarily by the Applicants or Co-Applicants in support of a benefit request);
- Physical Description (e.g., height, weight, eye color, hair color, identifying marks like tattoos or birthmarks);
- Criminal Records;
- Relationships to Sponsors, Representatives, Preparers, Co-Applicants and other Applicants;
- Signature (electronic or scanned physical signature).

Information about Sponsors may include:

- Full Name;
- Gender;
- Physical and Mailing Addresses:
  - Address;
  - Unit Number;
  - City;
  - State;
  - ZIP Code;
  - Postal Code;
  - U.S. County;
  - Province;
  - Country;
- Phone and Fax Numbers;
- Country of Domicile;
- Date of Birth;
- City of Birth;
- State of Birth;
- Province of Birth;
- Country of Birth;
- Citizenship Information;
- SSN;
- A-Number;
- Employment Information;
- Financial Information (e.g., income, expenses, scholarships, savings, assets, property, financial support, supporter information, life insurance, debts, encumbrances, tax records);
- Position and Relationship to an Organization (e.g., manager of a company seeking formal recognition by USCIS);
- Family Relationships (e.g., parent, spouse, sibling, child, other dependents)

and Relationship Practices (e.g., polygamy, custody, guardianship);

- Signature (electronic or scanned physical signature).

Information about Representatives may include:

- Name;
- Law Firm/Recognized Organization;
- Physical and Mailing Addresses;
- Phone and Fax Numbers;
- Email Address;
- Attorney Bar Card Number or Equivalent;
- Bar Membership;
- Accreditation Date;
- Board of Immigration Appeals Representative Accreditation;
- Expiration Date;
- Law Practice Restriction Explanation;
- Signature (electronic or scanned physical signature).

Information about Preparers and Interpreters may include:

- Full Name;
- Organization;
- Business State ID Number;
- Physical and Mailing Addresses:
  - Address;
  - Unit Number;
  - City;
  - State;
  - ZIP Code;
  - Postal Code;
  - U.S. County;
  - Province;
  - Country;
- Email Address;
- Phone and Fax Numbers;
- Paid/Not Paid (i.e., whether the Preparer or Interpreter was paid for assisting the Applicant or Sponsor in completing or submitting the benefit request);
- Relationship to Applicant;
- Signature (electronic or scanned physical signature).

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The Immigration and Nationality Act of 1952, Public Law 82–414, sections 101 and 103, as amended.

PURPOSE(S):

The purpose of this system is to provide an Applicant with a temporary account so that he or she may submit a benefit request through USCIS ELIS for the first time. USCIS ELIS collects draft benefit request information to assist the Applicant or Representative in providing all of the information necessary to request a benefit. If a first-time Applicant does not formally submit a benefit request within 30 days of opening the temporary account or initiating the draft benefit request, the information will be deleted. If an Applicant or Representative formally submits a benefit request within the 30-day window, USCIS converts the temporary account to a permanent USCIS ELIS account and retains the information according to the USCIS ELIS Account and Case Management SORN and USCIS ELIS Automated Background Functions SORN.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. § 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed outside DHS as a routine use pursuant to 5 U.S.C. § 552a(b)(3) as follows:

A. To appropriate agencies, entities, and persons when:

1. DHS suspects or has confirmed that the security or confidentiality of information in the system of records has been compromised;

2. DHS has determined that as a result of the suspected or confirmed compromise there is a risk of identity theft or fraud, harm to economic or property interests, harm to an individual, or harm to the security or integrity of this system or other systems or programs (whether maintained by DHS or another agency or entity) that relies upon the compromised information; and

3. The disclosure made to such agencies, entities, and/or persons is reasonably necessary to assist in connection with DHS's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

B. To contractors and their agents, grantees, experts, consultants, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for DHS, when necessary to accomplish an agency function related to this system of records. Individuals provided information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as are applicable to DHS officers and employees.

If a benefit request has been submitted to USCIS within 30 days of initiation, the information will become permanent and shared according to the routine uses listed in the Electronic Immigration System-2 Account and Case Management SORN and Electronic Immigration System-3 Automated Background Functions SORN in order to maintain USCIS ELIS accounts and determine eligibility for requested benefits.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

None.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records in this system are stored electronically in secure facilities. The records are stored on magnetic disc, tape, and/or digital media to maintain a real-time copy of the data for disaster recovery purposes. Real-time copies of data are deleted at the same time as the original data.

RETRIEVABILITY:

Records may be retrieved by any of the data elements listed above or by a combination thereof.

SAFEGUARDS:

Records in this system are safeguarded in accordance with applicable rules and policies, including all applicable DHS automated systems security and access policies. Strict controls have been imposed to minimize the risk of compromising the information that is being stored. Access to the computer system containing the records in this system is limited to those individuals who have a need to know the information for the performance of their official duties and who have appropriate clearances or permissions.

RETENTION AND DISPOSAL:

USCIS retains and disposes of temporary account and draft benefit request data in accordance with NARA approved schedule N1–566–11–02. After an Applicant registers for a USCIS ELIS account, the Applicant must begin drafting a benefit request within 30 days. If the Applicant does not begin drafting a benefit request within 30 days of creating a temporary account, USCIS ELIS considers the account abandoned and deletes the temporary account. If an Applicant with a temporary account does not submit a benefit request within 30 days of starting a draft benefit request, USCIS ELIS deletes the temporary account and all draft benefit request data. USCIS ELIS deletes all draft benefit request information 30 days after an Applicant or Representative begins, but fails to complete, the benefit submission process.

If an Applicant or Representative submits a benefit request within the 30-day window, USCIS retains the permanent account and benefit request information according to the Electronic Immigration System-2 Account and Case Management SORN and Electronic

Immigration System-3 Automated Background Functions SORN.

SYSTEM MANAGER AND ADDRESS:

The DHS system manager is the Chief, Office of Transformation Coordination, U.S. Citizenship and Immigration Services, Department of Homeland Security, 633 3rd Street NW., Washington, DC 20529.

NOTIFICATION PROCEDURE:

Individuals seeking notification of and access to any record contained in this system of records, or seeking to contest its content, may log in to USCIS ELIS to amend their information within the 30-day window. If the individual submits a benefit request, the information will still be available by logging in to the individual's USCIS ELIS account and may be amended through the processes described in the USCIS ELIS Account and Case Management SORN and USCIS ELIS Automated Background Functions SORN.

Because of the temporary nature of this data, records will not likely be available for FOIA requests. However, individuals seeking notification of and access to any record contained in this system of records, or seeking to contest its content, may submit a request in writing to the National Records Center (NRC) FOIA/PA Office, P.O. Box 648010, Lee's Summit, MO 64064–8010. NRC's contact information can be found at *http://www.dhs.gov/foia* under ''Contacts.'' If an individual believes that more than one component maintains Privacy Act records concerning him or her, the individual may submit the request to the Chief Privacy Officer and Chief Freedom of Information Act Officer, Department of Homeland Security, 245 Murray Drive SW., Building 410, STOP–0655, Washington, DC 20528.

When seeking records about yourself from this system of records or any other Departmental system of records, your request must conform with the Privacy Act regulations set forth in 6 C.F.R. Part 5. You must first verify your identity, meaning you must provide your full name, current address, and date and place of birth. You must sign your request, and your signature must either notarized or submitted under 28 U.S.C. § 1746, a law that permits statements to be made under penalty of perjury as a substitute for notarization. While no specific form is required, you may obtain forms for this purpose from the Chief Privacy Officer and Chief Freedom of Information Act Officer, *http://www.dhs.gov/foia* or 1–866–431–0486. In addition, you should:

- Explain why you believe the Department would have information on you;
- Identify which component(s) of the Department you believe may have the information about you;
- Specify when you believe the records would have been created; and
- Provide any other information that will help the FOIA staff determine which DHS component agency may have responsive records.

If your request is seeking records pertaining to another living individual, you must include a statement from that individual certifying his/her agreement for you to access his/her records.

Without the above information, the component(s) may not be able to conduct an effective search, and the request may be denied due to lack of specificity or lack of compliance with applicable regulations.

RECORD ACCESS PROCEDURES:

See ''Notification procedure'' above.

CONTESTING RECORD PROCEDURES:

See ''Notification procedure'' above.

RECORD SOURCE CATEGORIES:

Records are obtained from the Applicant, the primary Applicant for a Co-Applicant, Sponsor, his or her Representative, Preparer, or Interpreter.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

Dated: March 22, 2013.

Jonathan R. Cantor,

Acting Chief Privacy Officer, Department of Homeland Security.

[FR Doc. 2013–07770 Filed 4–4–13; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2013–0068]

Towing Safety Advisory Committee; Vacancies

AGENCY: United States Coast Guard.

ACTION: Request for applications.

SUMMARY: The United States Coast Guard (the Coast Guard) is requesting applications from qualified candidates seeking consideration for appointment as public members to the Towing Safety Advisory Committee (TSAC). TSAC advises the Coast Guard on matters relating to shallow-draft inland and coastal waterway navigation and towing safety.

DATES: Applications for TSAC membership must include a cover letter and resume. Note that all materials must be received on or before May 20, 2013.

ADDRESSES: Send your cover letter and resume via one of the following methods:

- *By mail:* Alternate Designated Federal Official (ADFO) of TSAC, Commandant, (CG–OES–2)/TSAC U.S. Coast Guard, 2100 Second St. SW., STOP 7126, Washington, DC 20593–7126;
- By fax to 202–372–1926; or
- By email to *William.J.Abernathy@uscg.mil*.

FOR FURTHER INFORMATION CONTACT: CDR Rob Smith, Designated Federal Official (DFO) of TSAC; telephone 202–372–1410; fax 202–372–1926; or email at *Robert.L.Smith@uscg.mil*.

SUPPLEMENTARY INFORMATION: TSAC is governed by the Federal Advisory Committee Act (FACA), 5 U.S.C. App. (Pub. L. 92–463) and was originally established in the Department of Transportation (Pub. L. 96–380, which was most recently amended by section 621 of the Coast Guard Authorization Act of 2010, Pub. L. 111–281). The Committee advises the Secretary of the Department of Homeland Security (DHS) on matters relating to shallow-draft inland and coastal waterway navigation and towing safety. This advice also assists the Coast Guard in formulating the position of the United States regarding the towing industry in advance of International Maritime Organization meetings.

The Committee meets at least twice a year either in the Washington DC area or in cities with large towing centers of commerce and populated by high concentrations of towing industry and related businesses. It may also meet for extraordinary purposes. Subcommittees may conduct intercessional telephonic meetings when necessary for specific tasking. The 18 members include:

- Seven members representing the Barge and Towing industry, reflecting a regional geographical balance.
- One member representing the offshore mineral and oil supply vessel industry.
- One member representing holders of active licensed Masters or Pilots of towing vessels with experience on the Western Rivers and the Gulf Intracoastal Waterway.
- One member representing the holders of active licensed Masters of towing vessels in offshore service.
- One member representing Masters who are active ship-docking or harbor towing vessels.
- One member representing licensed or unlicensed towing vessel engineers with formal training and experience.

• Two members representing Port districts, port authorities or terminal operators.

• Two members representing Shippers (of whom one must be engaged in the shipment of oil or hazardous materials by barge).

• Two members drawn from the General Public.

The Coast Guard is currently considering applications for six (6) positions that will become vacant on September 30, 2013:

• Three representatives from the Barge and Towing industry.

• One representative from port districts, port authorities or terminal operators.

• One person representing licensed or unlicensed towing engineers with formal training and experience.

• One person representing shippers.

To be eligible, applicants should have expertise, knowledge, and experience relative to the position in the towing industry, marine transportation, or business operations associated with shallow-draft inland and coastal waterway navigation and towing safety. Registered lobbyists are not eligible to serve on Federal advisory committees. Registered lobbyists are lobbyists required to comply with provisions contained in the Lobbying Disclosure Act of 1995 (Pub. L. 104–65, as amended by Title II of Pub. L. 110–81). Each member serves for a term up to three (3) years. Members may be considered to serve consecutive terms. All members serve at their own expense and receive no salary, or other compensation from the Federal Government.

DHS does not discriminate in employment on the basis of race, color, religion, sex, national origin, political affiliation, sexual orientation, gender identity, marital status, disabilities and genetic information, age, membership in an employee organization, or any other non-merit factor.

If you are interested in applying to become a member of the Committee, submit your application materials indicating the position you wish to fill; specify your area of expertise, knowledge and experience that qualify you for service on TSAC; and submit your complete package to ADFO William J. Abernathy via one of the transmittal methods provided above. Note that during the pre-selection vetting process, applicants may be asked to provide their date of birth and social security number.

To visit our online docket, go to *https://www.regulations.gov.* enter the docket number (USCG–2013–0068) in the Search box, and click ''Search''. Please do not post your resume on this site.

Dated: April 1, 2013.

J.G. Lantz,

Director of Commercial Regulations and Standards.

[FR Doc. 2013–07902 Filed 4–4–13; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

Aviation Security Advisory Committee (ASAC) Meeting

AGENCY: Transportation Security Administration, DHS.

ACTION: Committee Management; Notice of Closed Federal Advisory Committee Meeting.

SUMMARY: The Aviation Security Advisory Committee (ASAC) will meet in Arlington, VA. This meeting will be closed to the public.

FOR FURTHER INFORMATION CONTACT: Dean Walter, ASAC Designated Federal Officer, Transportation Security Administration (TSA–28), 601 South 12th Street, Arlington, VA 20598–4028, *Dean.Walter@dhs.gov*, 571–227–2645.

SUPPLEMENTARY INFORMATION:

Meeting Summary

Notice of this meeting is given under section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (Pub. L. 92–463). The Aviation Security Advisory Committee (ASAC) provides advice and makes recommendations to the Secretary of Homeland Security, via the Administrator of TSA, for approving civil aviation security measures.

The ASAC will meet to receive a classified briefing on threat intelligence related to TSA's prohibited items list. The ASAC also will receive a briefing on TSA risk-based initiatives pertaining to passenger prescreening.

Basis for Closure: In accordance with section 10(d) of the Federal Advisory Committee Act, it has been determined that the meeting requires closure. The meeting will be closed to the public in accordance with the provisions set forth under 5 U.S.C. 552b(c)(1), 552b(c)(3), 552b(c)(7)(E)–(F) and 552b(c)(9)(B), as amended.

TSA will be providing a classified (SECRET) briefing to the ASAC on threat intelligence related to TSA's prohibited items list. Specifically, there will be material presented regarding the latest viable threats against U.S. aviation security and how TSA plans to address those threats using a risk-based security framework. Properly classified material is protected from disclosure under 5 U.S.C. 552b(c)(1). Further, providing this information to the public could provide terrorists with a road map regarding TSA and DHS plans to counter their actions, and thus allow them to take different actions to avoid counterterrorism measures. Under 5 U.S.C. 552b(c)(7)(E)–(F), disclosure of this information could reveal investigative techniques and procedures not generally available to the public, allowing those with interests against the United States to circumvent the law, thereby endangering the life or physical safety of law enforcement personnel. Additionally, premature disclosure of this information would be likely to significantly frustrate the successful implementation of measures designed to counter terrorist acts. *See,* 5 U.S.C. 552b(c)(9)(B).

The ASAC also will receive a briefing on TSA risk-based initiatives pertaining to passenger prescreening, which will include lessons learned from existing screening procedures, enhanced security and improved traveler experience that may be realized by new risk-based initiatives, and screening techniques associated with such initiatives. The briefing will include sensitive security information, as that term is defined under 49 U.S.C. 114 (r) and 49 CFR part 1520. Sensitive security information includes information that would be detrimental to the security of transportation, and may not be disclosed to the general public. Accordingly, this portion of the meeting is closed under 5 U.S.C. 552b(c)(3). Further, premature public disclosure about this initiative would be likely to significantly frustrate implementation of a proposed agency action within the meaning of 5 U.S.C. 552b(c)(9)(B).

Closure of the April 22, 2013, ASAC meeting is warranted under 5 U.S.C. 552b(c)(1), (c)(3), (c)(7)(E)–(F) and (c)(9)(B).

Accordingly, this meeting will be closed to the public.

Issued in Arlington, Virginia, on April 3, 2013.

John P. Sammon,

Assistant Administrator, Security Policy and Industry Engagement.

[FR Doc. 2013–08129 Filed 4–4–13; 8:45 am]

BILLING CODE 9110–05–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5681–N–14]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for use to assist the homeless.

FOR FURTHER INFORMATION CONTACT: Juanita Perry, Department of Housing and Urban Development, 451 Seventh Street SW., Room 7266, Washington, DC 20410; telephone (202) 402–3970; TTY number for the hearing- and speech-impaired (202) 708–2565 (these telephone numbers are not toll-free), or call the toll-free Title V information line at 800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with 24 CFR part 581 and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless* v. *Veterans Administration,* No. 88–2503–OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, and suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Where property is described as for ''off-site use only'' recipients of the property will be required to relocate the building to their own site at their own expense. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, addressed to Theresa Ritta, Division of Property Management, Program Support Center, HHS, room 5B–17, 5600 Fishers Lane, Rockville, MD 20857; (301) 443–2265. (This is not a toll-free number.) HHS will mail to the interested provider an application packet, which will include instructions for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 24 CFR part 581.

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time, HUD will publish the property in a Notice showing it as either suitable/available or suitable/unavailable.

For properties listed as suitable/unavailable, the landholding agency has decided that the property cannot be declared excess or made available for use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other purpose for 20 days from the date of this Notice. Homeless assistance providers interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1–800–927–7588 for detailed instructions or write a letter to Ann Marie Oliva at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), the date of publication in the **Federal Register**, the landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (i.e., acreage, floor plan, existing sanitary facilities, exact street address), providers should contact the appropriate landholding agencies at the following addresses: *Agriculture:* Ms. Brenda Carignan, Department of Agriculture, Reporters Building, 300 7th Street SW., Room 337, Washington, DC 20024, (202) 401–0787; *Army:* Ms. Veronica Rines, Office of the Assistant Chief of Staff for Installation Management, Department of Army, Room 5A128, 600 Army Pentagon, Washington, DC 20310, (571) 256–8145; *Coast Guard:* Commandant, United States Coast Guard, Attn: Jennifer Stomber, 2100 Second St. SW., Stop 7901, Washington, DC 20593–0001; (202) 475–5609; *NASA:* Mr. Frank T. Bellinger, Facilities Engineering Division, National Aeronautics & Space Administration, Code JX, Washington, DC 20546, (202) 358–1124; *Navy:* Mr. Steve Matteo, Department of the Navy, Asset Management Division, Naval Facilities Engineering Command, Washington Navy Yard, 1322 Patterson Avenue SE., Ste. 1000, Washington, DC 20374, (202) 685–9426; (These are not toll-free numbers).

Dated: March 28, 2013.

Mark Johnston,

Deputy Assistant Secretary for Special Needs.

TITLE V, FEDERAL SURPLUS PROPERTY PROGRAM FEDERAL REGISTER REPORT FOR 04/05/2013

Suitable/Available Properties

Building

Massachusetts

Generator Bldg.
North Reservation Terrace
Plum Island MA 01950
Landholding Agency: Coast Guard
Property Number: 88201310003
Status: Excess
Comments: off-site removal; 144 sf.; very poor conditions; restricted area; contact Coast Guard for accessibility/removal reqs.

Tower Storage Bldg.
Miacomet
Nantucket MA 02554
Landholding Agency: Coast Guard
Property Number: 88201310004
Status: Excess
Comments: off-site removal only; 600 sf.; very poor conditions; restricted area; contact Coast Guard for accessibility/removal reqs.

Tower Storage Bldg.
900 Ferry St.
Marshfield MA 02050
Landholding Agency: Coast Guard
Property Number: 88201310005
Status: Excess
Comments: off-site removal only; 300 sf.; very poor conditions; restricted area; contact Coast Guard for accessibility/removal reqs.

New York

Housing Units
424 USS North Carolina Rd.
Staten Island NY 10305
Landholding Agency: Coast Guard
Property Number: 88201310008
Status: Excess
Comments: off-site removal only; 16,638 sf.; housing; very poor conditions; secured area; contact Coast Guard for accessibility/removal reqs.

Texas

Building 41
2101 NASA Parkway
Houston TX 77058
Landholding Agency: NASA
Property Number: 71201310003
Status: Unutilized
Comments: 671 sf.; office/shop; deteriorated conditions; remediation needed; restricted access; stringent accessibility reqs.; contact Sandra J. Tetley at sandra.j.tetley@nasa.gov for more info.

Suitable/Unavailable Properties

Building

Washington

Willard Pole #2309
201 Oklahoma Rd.
Willard WA 98605
Landholding Agency: Agriculture
Property Number: 15201310020
Status: Excess
Comments: 3,500 sf.; repairs needed; restricted area; contact USDA for accessibility/removal reqs.

Wil Garage #1510 & 1511
201 Oklahoma Rd.
Willard WA 98605
Landholding Agency: Agriculture
Property Number: 15201310021
Status: Excess
Comments: 480 sf. for ea. bldg.; storage; repairs needed; restricted area; contact USDA for accessibility/removal reqs.

Unsuitable Properties

Building

Florida

Building 798
NAS
Jacksonville FL
Landholding Agency: Navy
Property Number: 77201310004
Status: Underutilized
Comments: located on restricted naval air station; public access denied & no alternative method to gain access w/out compromising nat'l security
Reasons: Secured Area

Maryland

Shed
2401 Hawkins Point Rd.
Baltimore MD 21226
Landholding Agency: Coast Guard
Property Number: 88201310007
Status: Excess
Comments: located on an active military facility; public access denied & no alternative method to gain access w/out compromising nat'l security
Reasons: Secured Area

Massachusetts

Emergency Response Storage
54 Tillson Ave.
Rockland MA 04841
Landholding Agency: Coast Guard
Property Number: 88201310006
Status: Excess
Comments: public access denied & no alternative method to gain access w/out compromising nat'l security
Reasons: Secured Area

Washington

10 Buildings
Joint Base Lewis McChord
JBLM WA 98433
Landholding Agency: Army
Property Number: 21201310066
Status: Underutilized
Directions: 03154, 03156, 03157, 03158, 03160, 03161, 03163, 03164, 03165, 03167
Comments: secured military cantonment area; public access denied & no alternative method to gain access w/out compromising nat'l security
Reasons: Secured Area

[FR Doc. 2013–07686 Filed 4–4–13; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R5–R–2012–N136: BAC–4311–K9–S3]

Nantucket National Wildlife Refuge, Nantucket, MA; Final Comprehensive Conservation Plan and Finding of No Significant Impact

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce the availability of our final comprehensive conservation plan (CCP), finding of no significant impact (FONSI), and land protection plan (LPP) for Nantucket National Wildlife Refuge (NWR, refuge) in Nantucket, Massachusetts. Nantucket NWR is part of the Eastern Massachusetts NWR Complex, administered from Sudbury, Massachusetts. In this final CCP, we describe how we will manage the refuge for the next 15 years.

ADDRESSES: You may view or obtain copies of the final CCP and FONSI by any of the following methods. You may request a hard copy or a CD–ROM.

Agency Web site: Download a copy of the document at *http://www.fws.gov/northeast/planning/nantucket/ccphome.html.*

Email: Send requests to *northeastplanning@fws.gov.* Include ''Nantucket Refuge CCP'' in the subject line of your message.

Mail: Carl Melberg, Natural Resource Planner, U.S. Fish and Wildlife Service, 73 Weir Hill Road, Sudbury, MA 01776.

Fax: Attention: Carl Melberg, 978–443–2898.

In-Person Viewing or Pickup: Call 978–443–4661 to make an appointment during regular business hours at the Sudbury office, 73 Weir Hill Road, Sudbury, MA 01776.

FOR FURTHER INFORMATION CONTACT: Libby Herland, Refuge Manager, Nantucket NWR, 73 Weir Hill Road, Sudbury, MA 01776; 978–443–4661 (phone); 978–443–2898 (fax); *libby_herland@fws.gov* (email).

SUPPLEMENTARY INFORMATION:

Introduction

With this notice, we finalize the CCP process for Nantucket NWR. We started this process through a notice in the **Federal Register** (64 FR 9166; February 24, 1999), announcing we were preparing a CCP and environmental impact statement (EIS) for all eight refuges in what was then known as the Great Meadows NWR Complex. In 2001, we determined it was not feasible to prepare a single CCP for all eight refuges, and thus prepared another notice in the **Federal Register** (66 FR 10506; February 15, 2001), to indicate that a separate CCP/environmental assessment (EA) would be prepared for Great Meadows, Assabet River, and Oxbow NWRs. We planned to prepare a separate CCP for the other five refuges in the refuge complex, including Nantucket NWR. However, in 2008, because of the different issues facing those five refuges, the Service determined it was more efficient to proceed through the CCP process for each refuge separately, and published a notice in the **Federal Register** (73 FR 18806; April 7, 2008), to begin a separate CCP/EA process for Nantucket NWR. We released the draft CCP/EA for Nantucket NWR to the public, announcing and requesting comments in a notice of availability in the **Federal Register** on August 2, 2011 (76 FR 46317).

The Service established Nantucket NWR in 1973, under an Act Authorizing the Transfer of Certain Real Property for Wildlife, or other Purposes (16 U.S.C. 667b, Pub. L. 80–537), which authorized the U.S. Coast Guard (USCG) to transfer the property to the Service because of ''its particular value in carrying out the Migratory Bird Act.'' The USCG currently maintains control of a 1-acre inholding on the refuge that contains the Great Point Lighthouse. Nantucket NWR lies at the northern tip of the Coskata-Coatue Peninsula, which is also known as Great Point. The peninsula is at the northernmost point of Nantucket Island.

The only access to the refuge by land is through The Trustees of Reservations' (TTOR) Coskata-Coatue Refuge and Nantucket Conservation Foundation (NCF) properties from the south. The refuge erodes and accretes constantly, but averages 21 acres in size. The refuge is a barrier beach system where two longshore currents meet to form a rip current. The refuge is composed of

beach and dune habitat that supports a diversity of sea and land birds of conservation concern, including common and roseate terns, piping plover, and American oystercatcher, and Federal trust marine mammals, such as gray seals.

We announce our decision and the availability of the FONSI for the final CCP for Nantucket NWR in accordance with National Environmental Policy Act (NEPA) (42 U.S.C. 4321 *et seq.*) requirements. We completed a thorough analysis of impacts on the human environment, which we included in the draft CCP/EA.

The CCP will guide us in managing and administering Nantucket NWR for the next 15 years. Alternative B, as described for the refuge in the draft CCP/EA, and with the modifications described below, is the foundation for the final CCP.

Background

The National Wildlife Refuge System Administration Act of 1966 (16 U.S.C. 668dd–668ee) (Refuge Administration Act), as amended by the National Wildlife Refuge System Improvement Act of 1997, requires us to develop a CCP for each NWR. The purpose for developing a CCP is to provide refuge managers with a 15-year plan for achieving refuge purposes and contributing toward the mission of the National Wildlife Refuge System (NWRS), consistent with sound principles of fish and wildlife management, conservation, legal mandates, and our policies. In addition to outlining broad management direction on conserving wildlife and their habitats, CCPs identify wildlife-dependent recreational opportunities available to the public, including opportunities for hunting, fishing, wildlife observation and photography, and environmental education and interpretation. We will review and update the CCP at least every 15 years in accordance with the Refuge Administration Act.

CCP Alternatives, Including the Selected Alternative

Our draft CCP/EA (76 FR 46317) addressed several key issues, including:

- Providing habitat protection and management for federally endangered and threatened species and other protected wildlife.
- Maintaining a balance between resource protection and beach access, and determining compatibility for recreational uses.
- Increasing education and interpretation of the resources, and increasing communications about management decisions.
- Cooperating in land management with adjacent land managers and planning for future land acquisition opportunities.
- Creating a protocol for ensuring cultural resource protection.

To address these issues and develop a plan based on the refuge's establishing purposes, vision, and goals, we evaluated three alternatives for Nantucket NWR in the draft CCP/EA. The alternatives for Nantucket NWR have some actions in common, such as protecting the beach and dune habitat and the bird species of conservation concern using this habitat, providing wildlife-dependent priority public uses when compatible, reducing impacts from climate change, protecting cultural resources, and distributing refuge revenue sharing payments to the town of Nantucket, Massachusetts. There are other actions that differ among the alternatives. The draft CCP/EA describes each alternative in detail and relates them to the issues and concerns that arose during the planning process. Below, we provide summaries for the three alternatives evaluated in the draft CCP/EA.

Alternative A (Current Management)

This alternative is the ''No Action'' alternative required by the National Environmental Policy Act (42 U.S.C. 4321 *et seq*). It defines our current management activities, including those planned, funded, or underway, and serves as the baseline against which to compare alternatives B and C. This alternative describes current refuge programs on the 21-acre refuge for habitat management, fish and wildlife inventories and monitoring, administrative infrastructure and staffing, and visitor services. Under this alternative, TTOR would continue to provide onsite management of Nantucket NWR, and the Service would continue its passive management role and minimal presence on the refuge. The remote location of the refuge, along with limited staffing and funding resources, restricts our ability to maintain a consistent presence, or to actively oversee and implement management actions. Instead, we would continue to coordinate with TTOR for installing symbolic fencing and implementing beach closures to protect breeding and staging birds and seal haul-out sites on the refuge.

Under alternative A, the Service would maintain oversight, but visitor services programs would continue to be implemented primarily by partners, such as TTOR. Priority public uses, such as wildlife observation, photography, environmental education, interpretation, and fishing are currently allowed on the refuge and would continue where beach access is permitted. Hunting is the only priority public use that is not allowed on the refuge due to the refuge's small size and habitat types. Under this alternative, all staff would continue to be stationed at the Eastern Massachusetts NWR Complex headquarters in Sudbury, Massachusetts. We would continue discussions to pursue a partnership agreement with TTOR, which would include resource management, visitor use, and shared funding sources to help contribute to refuge operations.

Alternative B (Enhanced Wildlife and Visitor Services Emphasis)

This is the Service-preferred alternative. It combines the actions we believe would best achieve the refuge's purposes, vision, and goals, and the intent of NWRS policy on Biological Integrity, Diversity, and Environmental Health (601 FW 3). This alternative would also best respond to the issues that arose during the planning process. Alternative B would improve our management of refuge habitats and species of conservation concern, with increased Service presence on the existing 21-acre refuge, and on the additional 2,036 acres proposed for Service acquisition from willing sellers in fee or easement, or as a no-cost transfer from other Federal agencies. It strives to provide a balance between habitat and species conservation and public use and access. It would enhance partnerships with local conservation organizations and civic groups.

Under this alternative, the Service would take a more active role in habitat and species management on the refuge, targeting the protection of dynamic coastal beach and dune systems and the species that rely on them for critical nesting, resting, foraging, and staging habitat. The additional protection proposed may result in increased public recreational access restrictions or closures on the refuge during certain seasons or in some years.

We would also continue to work closely with TTOR, NCF, and our other partners to accomplish biological program priorities with an emphasis on landscape-level conservation and more consistent management between peninsula partners. A draft LPP, which requires Director's approval before it can be implemented, was included as Appendix G in the draft CCP/EA. The LPP proposes that 2,036 acres of high resource value be acquired for the refuge if willing sellers are available.

Under alternative B, we would establish public use zones that would allow some increased public use opportunities in certain areas where wildlife are less likely to be disturbed, with an emphasis on providing fishing, wildlife observation, environmental education, and interpretation. An increase in opportunities would also be accomplished by working with partners to monitor wildlife use and offer visitor programs. We propose to add a part-time, year-round visitor services specialist and a full-time biologist stationed on Nantucket Island, and a new law enforcement officer stationed at Monomoy NWR in Chatham, Massachusetts.

Alternative C (Emphasis on Wildlife Diversity and Natural Processes)

This alternative would focus on managing wildlife diversity and natural coastal processes. It would emphasize species and habitat protection on the refuge through actions such as not allowing over-sand vehicles for fishing access on most of the refuge during April 1 through September 15. Staff would monitor and evaluate nesting success and productivity for priority bird species of conservation concern. Alternative C includes expanding current management and staffing over the next 15 years on the refuge. It would also involve targeted fee and easement acquisition of excess and surplus Federal lands and other key conservation properties on Nantucket Island as opportunities arise. Visitor services would be similar to those under alternative B, except for the longer, more restrictive over-sand vehicle closure zones. Similar to alternative B, this alternative proposes a joint visitor facility with TTOR and NCF, as well as increased visitor services programming and opportunities through partners.

Comments

We solicited comments on the draft CCP/EA for Nantucket NWR from August 2 to October 1, 2011 (76 FR 46317). During the comment period, we received 38 written responses. We evaluated all of the substantive comments we received, and include a summary of those comments, and our responses to them, as Appendix J in the final CCP.

Selected Alternative

After considering the comments we received on our draft CCP/EA, we have made several minor changes to alternative B. These changes are described in the final CCP in the FONSI (Appendix L) and in Appendix J.

We have selected alternative B to implement for Nantucket NWR, with these minor changes, for several reasons. Alternative B comprises a mix of actions that, in our professional judgment, work best towards achieving the refuge's purposes, vision, and goals; NWRS policies; and the goals of other State and regional conservation plans. Our ability to achieve conservation goals is further enhanced with the land protection plan (LPP) included in alternative B. The LPP was approved by the Service's Director on January 15, 2013. We also believe that alternative B most effectively addresses key issues raised during the planning process. The basis of our decision is also detailed in the FONSI.

Public Availability of Documents

You can view or obtain the final CCP, including the FONSI, as indicated under **ADDRESSES**.

Dated: February 18, 2013.

Deborah Rocque,

Acting Regional Director, Northeast Region.

[FR Doc. 2013–07937 Filed 4–4–13; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R4–ES–2013–N076; FXES11130400000EA–123–FF04EF1000]

Endangered and Threatened Wildlife and Plants; Receipt of Application for Renewal of Incidental Take Permit; Availability of Proposed Low-Effect Habitat Conservation Plan; Eber Cove, LLC, Brevard County, FL

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comments.

SUMMARY: We, the Fish and Wildlife Service (Service), have received an application from Eber Cove, LLC (applicant), for a 5-year renewal of incidental take permit (ITP) TE151089–0 under the Endangered Species Act of 1973, as amended (Act). We request public comment on the permit application and accompanying proposed habitat conservation plan (HCP), as well as on our preliminary determination that the plan qualifies as low effect under the National Environmental Policy Act (NEPA). To make this determination, we used our environmental action statement and low-effect screening form, which are also available for review.

DATES: To ensure consideration, please send your written comments by May 6, 2013.

ADDRESSES: If you wish to review the application and HCP, you may request documents by email, U.S. mail, or phone (see below). These documents are also available for public inspection by appointment during normal business hours at the office below. Send your comments or requests by any one of the following methods.

Email: northflorida@fws.gov. Use ''Attn: Permit number TE151089–1'' as your message subject line.

Fax: Dawn Jennings, Acting Field Supervisor, 904–731–3045, Attn.: Permit number TE151089–1.

U.S. mail: Dawn Jennings, Acting Field Supervisor, Jacksonville Ecological Services Field Office, Attn: Permit number TE151089–1, U.S. Fish and Wildlife Service, 7915 Baymeadows Way, Suite 200, Jacksonville, FL 32256.

In-person drop-off: You may drop off information during regular business hours at the above office address.

FOR FURTHER INFORMATION CONTACT: Erin M. Gawera, telephone: 904–731–3121; email: *erin_gawera@fws.gov.*

SUPPLEMENTARY INFORMATION:

Background

Section 9 of the Act (16 U.S.C. 1531 et seq.) and our implementing Federal regulations in the Code of Federal Regulations (CFR) at 50 CFR 17 prohibit the ''take'' of fish or wildlife species listed as endangered or threatened. Take of listed fish or wildlife is defined under the Act as ''to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct'' (16 U.S.C. 1532). However, under limited circumstances, we issue permits to authorize incidental take—i.e., take that is incidental to, and not the purpose of, the carrying out of an otherwise lawful activity.

Regulations governing incidental take permits for threatened and endangered species are at 50 CFR 17.32 and 17.22, respectively. The Act's take prohibitions do not apply to federally listed plants on private lands unless such take would violate State law. In addition to meeting other criteria, an incidental take permit's proposed actions must not jeopardize the existence of federally listed fish, wildlife, or plants.

Applicant's Proposal

The applicant has been approved for take of approximately 1.55 acres (ac) of Florida scrub-jay (*Aphelocoma coerulescens*)–occupied habitat incidental to construction of a single-family-home subdivision. The 28.25-ac

project is located on Parcel #28–37–17–00–00753.0–0000.00 and #28–37–17–00–00769.0–0000.00, within Section 17, Township 28 South, Range 37 East, Brevard County, Florida. The applicant's HCP describes the mitigation and minimization measures the applicant proposes to address the effects of the project to the Florida scrub-jay.

Our Preliminary Determination

We have determined that the applicant's proposal, including the proposed mitigation and minimization measures, would have minor or negligible effects on the species covered in the HCP. Therefore, we determined that the ITP is a low-effect project and qualifies for categorical exclusion under the National Environmental Policy Act (NEPA), as provided by the Department of the Interior Manual (516 DM 2 Appendix 1 and 516 DM 6 Appendix 1). A low-effect HCP is one involving (1) minor or negligible effects on federally listed or candidate species and their habitats, and (2) minor or negligible effects on other environmental values or resources.

Next Steps

We will evaluate the HCP and comments we receive to determine whether the ITP application meets the requirements of section 10(a) of the Act (16 U.S.C. 1531 et seq.). If we determine that the application meets these requirements, we will issue the ITP. We will also evaluate whether issuance of the section 10(a)(1)(B) ITP complies with section 7 of the Act by conducting an intra-Service section 7 consultation. We will use the results of this consultation, in combination with the above findings, in our final analysis to determine whether or not to issue the ITP. If the requirements are met, we will issue the permit to the applicant.

Public Comments

If you wish to comment on the permit application, HCP, and associated documents, you may submit comments by any one of the methods in **ADDRESSES**.

Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comments, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority

We provide this notice under Section 10 of the Act and NEPA regulations (40 CFR 1506.6).

Dated: March 27, 2013.

Dawn Jennings,

Acting Field Supervisor, Jacksonville Field Office, Southeast Region.

[FR Doc. 2013–07929 Filed 4–4–13; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R3–ES–2013–0032: FXES11120300000F2–134–FF03E00000]

Draft Environmental Impact Statement, Draft Habitat Conservation Plan, Draft Programmatic Agreement, and Draft Implementing Agreement; Application for an Incidental Take Permit, Fowler Ridge Wind Farm, Benton County, Indiana

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), have received an application from Fowler Ridge Wind Farm LLC, Fowler Ridge II Wind Farm LLC, Fowler Ridge III Wind Farm LLC, and Fowler Ridge IV Wind Farm LLC, collectively referred to as Fowler Ridge (applicant), for an incidental take permit (ITP) under the Endangered Species Act of 1973, as amended (ESA), for its Fowler Ridge Wind Farm (FRWF) (project). If approved, the ITP would be for a 22-year period and would authorize the incidental take of an endangered species, the Indiana bat. The applicant has prepared a draft habitat conservation plan (HCP) that describes the actions and measures that the applicant would implement to avoid, minimize, and mitigate incidental take of the Indiana bat. The ITP application also includes a draft implementing agreement (IA). We also announce the availability of a draft Environmental Impact Statement (DEIS), which has been prepared in response to the permit application in accordance with the requirements of the National Environmental Policy Act (NEPA), and a draft Programmatic Agreement (PA) that has been prepared in response to the permit application in accordance with the National Historic Preservation Act (NHPA). We request public comment on the application and associated documents.

DATES: *Public Meeting:* Thursday, April 18, 2013 from 4 to 8 p.m. local time (EST) at the Benton County Government Annex, 410 South Adeway, Suite A, Fowler, IN 47944.

Comments: We will accept comments received or postmarked on or before June 4, 2013. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES** section, below) must be received by 11:59 p.m. Eastern Time on the closing date.

ADDRESSES: *Document availability:*

- *Internet:* You may obtain copies of the documents on the Internet at *http://www.regulations.gov* (Docket Number FWS–R3–ES–2013–0032) or *http://www.fws.gov/midwest/endangered/permits/hcp/r3hcps.html.*
- *U.S. Mail:* You can obtain the documents by mail from the Indiana Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).
- *In-Person:* To view hard copies of the documents in person, go to one of the Ecological Services Offices (8 a.m. to 4 p.m.) listed under **FOR FURTHER INFORMATION CONTACT**, or to one of the following libraries during normal business hours: Benton County Public Library, 765–884 –1720, 102 N. Van Buren Avenue, Fowler, IN 47944; or Otterbein Public Library (*www.otterbeinpubliclibrary.org*), 765–583–2107, 23 E. 1st Street, Otterbein, IN 47970.

Public Meeting: See **DATES**.

Comment submission: In your comment, please specify whether your comment addresses the draft HCP, draft EIS, draft PA, or draft IA, or any combination of the aforementioned documents, or other supporting documents. You may submit written comments by one of the following methods:

- *Electronically:* Go to the Federal eRulemaking Portal: *http://www.regulations.gov.* In the Search box, enter FWS–R3–ES–2013–0032, which is the docket number for this notice. Then, on the left side of the screen, under the Document Type heading, click on the Notices link to locate this document and submit a comment.
- *By hard copy:* Submit by U.S. mail or hand-delivery to: Public Comments Processing, Attn: FWS–R3–ES–2013–0032; Division of Policy and Directives Management; U.S. Fish and Wildlife Service; 4401 N. Fairfax Drive, MS 2042–PDM; Arlington, VA 22203.

We request that you send comments only by the methods described above. We will post all information received on *http://www.regulations.gov.* This generally means that we will post any

personal information you provide us (see the Public Comments section below for more information).

FOR FURTHER INFORMATION CONTACT: Scott Pruitt, Field Supervisor, Bloomington, Indiana, Ecological Services Field Office, U.S. Fish and Wildlife Service, 620 South Walker Street, Bloomington, IN 47403; telephone: 812–334–4261, extension 214; or Rick Amidon, Fish and Wildlife Biologist, Ecological Services, Midwest Regional Office, U.S. Fish and Wildlife Service, 5600 American Blvd., West, Suite 990, Bloomington, MN 55437–1458; telephone: 612–713–5164.

SUPPLEMENTARY INFORMATION: We have received an application from Fowler Ridge Wind Farm LLC, Fowler Ridge II Wind Farm LLC, Fowler Ridge III Wind Farm LLC, and Fowler Ridge IV Wind Farm LLC, collectively referred to as Fowler Ridge, for an incidental take permit (TE95012A) under the ESA (16 U.S.C. 1531 *et seq.*). If approved, the ITP would be for a 22-year period and would authorize incidental take of the endangered Indiana bat (*Myotis sodalis*).

The applicant has prepared a draft HCP that covers the operation of Phases I–IV of the project. The project consists of a wind-powered electric generation facility located in an approximately 72,947-acre area (the project area including a one-half-mile buffer around the outside turbines) in Benton County, Indiana. The draft HCP describes the following: (1) Biological goals and objectives of the HCP; (2) covered activities; (3) permit duration; (4) project area; (5) alternatives to the taking that were considered; (5) public participation; (6) life history of the Indiana bat; (6) quantification of the take for which authorization is requested; (7) assessment of direct and indirect effects of the taking on the Indiana bat within the Midwest Recovery Unit (as delineated in the 2007 Indiana Bat Draft Recovery Plan, Service) and rangewide; (8) a conservation program consisting of avoidance and minimization measures, mitigation, monitoring, and adaptive management; (9) funding for the HCP; (10) procedures to deal with changed and unforeseen circumstances; and (11) methods for ITP amendments.

In addition to the draft HCP, the applicant has prepared a draft IA to document the responsibilities of the parties. The Service invites comment on the IA as well as the applicants' HCP.

Pursuant to the NHPA (16 U.S.C. 470, 470f), the Service has initiated Section 106 consultation with the Indiana State Historic Preservation Office regarding the construction of turbines under Phase IV of the FRWF project and the implementation of mitigation projects in accordance with the terms of the HCP. Sites have not been selected for the Phase IV turbines or for the mitigation. Therefore, future efforts will be required to identify archaeological sites that may be adversely affected by the construction of Phase IV turbines and implementation of mitigation. Following siting of the Phase IV turbines and location of mitigation sites, archaeological surveys will be conducted, with plans and reports submitted to the Indiana State Historic Preservation Office for review. The draft PA between the Service, Fowler Ridge, and the Indiana State Historic Preservation Office describes the process for conducting the surveys, evaluating the results of the surveys, and determining if resources can be avoided or if additional surveys or mitigation are necessary before the Section 106 process is completed. The final PA will be signed prior to issuance of the EIS Record of Decision. The Section 106 process will be completed and a memorandum of agreement signed prior to construction or mitigation beginning. Public comments are solicited on the content of the draft PA.

Under the NEPA (43 U.S.C. 4321 *et seq.*) and the ESA, the Service announces that we have gathered the information necessary to:

1. Determine the impacts and formulate alternatives for an EIS related to:

a. Issuance of an ITP to the applicant for the take of the Indiana bat, and

b. Implementation of the associated HCP; and

2. Evaluate the application for ITP issuance, including the HCP, which provides measures to minimize and mitigate the effects of the proposed incidental take of the Indiana bat.

Background

The Fowler Ridge application is unusual in that 355 wind turbines are already in place and have been operational since 2009. At the time of their construction, no Indiana bats had been documented to have been killed by a commercial wind facility (the first Indiana bat fatality was found at FRWF during monitoring in 2009). The turbines were constructed in three phases with a total energy capacity of 600 megawatts (MW). The 301.3–MW Fowler Phase I was constructed in 2008 and consists of 40 Clipper Liberty wind turbine generators (WTG) with a capacity of 2.5 MW per turbine and 122 Vestas V82 WTGs with a capacity of 1.65 MW per turbine. The 199.5–MW Fowler Phase II was constructed in 2009 and began operating later that year. The site consists of 133 GE WTGs, each with a 1.5–MW capacity. The 99–MW Fowler Phase III was constructed in 2008 and began operating in 2009. The site consists of 60 Vestas V82 WTGs, each with a 1.65–MW capacity per turbine. Phase IV will consist of up to 94 GE 1.6–MW turbines for a total capacity of 150.4 MW. Currently, Phase IV is planned for construction in 2014. The need for the proposed action (*i.e.,* issuance of an ITP) is based on finding two dead Indiana bats at the facility, the aforementioned 2009 fatality and another in 2010, and the potential that future operation of FRWF could result in additional take of Indiana bats.

The HCP provides a detailed conservation plan to ensure that the incidental take caused by the operation of the project will not appreciably reduce the likelihood of the survival and recovery of the Indiana bat in the action area or in the recovery unit, and provides mitigation to fully offset the impact of the taking. Further, the HCP provides a long-term monitoring and adaptive management strategy to ensure that the ITP terms are satisfied, and to account for changed and unforeseen circumstances.

Purpose and Need for Action

In accordance with NEPA, the Service has prepared an EIS to analyze the impacts to the human environment that would occur if the requested ITP were issued and the associated HCP were implemented.

Proposed Action

Section 9 of the ESA prohibits the ''taking'' of threatened and endangered species. However, provided certain criteria are met, the Service is authorized to issue permits under section 10(a)(1)(B) of the ESA for take of federally listed species when, among other things, such a taking is incidental to, and not the purpose of, otherwise lawful activities. Under the ESA, the term ''take'' means to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect endangered and threatened species, or to attempt to engage in any such conduct. Our implementing regulations define ''harm'' as an act which actually kills or injures wildlife, and such act may include significant habitat modification or degradation that results in death or injury to listed species by significantly impairing essential behavioral patterns, including breeding, feeding, or sheltering (50 CFR 17.3). Harass, as defined, means ''an intentional or negligent act or omission which creates the likelihood of injury to wildlife by

annoying it to such an extent as to significantly disrupt normal behavioral patterns which include, but are not limited to, breeding, feeding, or sheltering'' (50 CFR 17.3).

The HCP analyzes, and the ITP would cover, take from harassment, harm, and killing of bats due to the operation of the FRWF project. If issued, the ITP would authorize incidental take consistent with the applicant's HCP and the ITP. To issue the ITP, the Service must find that the application, including its HCP, satisfies the criteria of section 10(a)(1)(B) of the ESA and the Service's implementing regulations at 50 CFR parts 13 and 17.22. If the ITP is issued, the applicant would receive assurances under the Service's No Surprises policy, as codified at 50 CFR 17.22(b)(5).

The applicant proposes to construct 94 turbines under Phase IV and operate a maximum of 449 wind turbines and associated facilities (described below) for a period of 22 years in Benton County, Indiana. The project will consist of wind turbines, associated access roads, an underground and aboveground electrical collector system, four substations (one for each phase of the project) containing six transformers that feed electricity into an existing 345-kilovolt (kV) electrical tie-in line (roughly 200 poles carrying electricity approximately 50 km (31 mi) to the existing Dequine Substation in Tippecanoe County), seven permanent un-guyed 80-m tall meteorological towers, and an operations and maintenance building. Project facilities and infrastructure will be placed on private land via long-term easement agreements between the applicant and respective landowners.

While approximately 6,400 acres are located within the Phase IV project area, a relatively small portion of that land, approximately 554 acres, will be disturbed, and only 78.2 acres will be permanently occupied by the Phase IV facilities. The FRWF project area is 93-percent row crop agriculture. Phases I–III have been in operation since 2009 within this agricultural context. Beyond the area required for construction, Phase IV is not expected to change current land use.

The draft HCP describes the impacts of take associated with the operation of the FRWF and includes measures to avoid, minimize, mitigate, and monitor the impacts of incidental take on the Indiana bat. The applicant will mitigate for take and associated impacts through protection of a Priority 1 hibernaculum and restoration and protection of maternity colony habitat at one or more documented maternity colonies. Maternity colony habitat mitigation, including any restored habitat, will occur on private land and be permanently protected by restrictive covenants approved by the Service. Chapter 5 of the HCP describes the Conservation Program, including details of avoidance and minimization measures, compensatory mitigation, and adaptive management that will limit and mitigate for the take of Indiana bats.

The Service is soliciting information regarding the adequacy of the HCP to avoid, minimize, mitigate, and monitor the proposed incidental take of the covered species and to provide for adaptive management. In compliance with section 10(c) of the ESA (16 U.S.C. 1539(c)), the Service is making the ITP application materials available for public review and comment as described above.

We invite comments and suggestions from all interested parties on the draft documents associated with the ITP application (HCP, HCP Appendices, and IA), and request that comments be as specific as possible. In particular, we request information and comments on the following topics:

1. Whether adaptive management and monitoring provisions in the Proposed Action alternative are sufficient;
2. Any threats to the Indiana bat that may influence its population over the life of the ITP that are not addressed in the draft HCP or draft EIS;
3. Any new information on white-nose syndrome effects on the Indiana bat;
4. Any other information pertinent to evaluating the effects of the proposed action on the Indiana bat.

Alternatives in the Draft EIS

The DEIS contains an analysis of four alternatives: (1) No Action alternative, in which all 449 turbines would be shut down (*i.e.,* non-operational) from sunset to sunrise from August 1 through October 15, the primary fall migratory period of the Indiana bat, each year during the operational life (22 years) of the FRWF; (2) The 3.5 m/s Cut-In Speed (Feathered) Alternative, including implementation of the HCP and issuance of a 22-year ITP; (3) the 5.0 m/s Cut-In Speed (Feathered) Alternative, including implementation of the HCP and issuance of a 22-year ITP; and (4) the 6.5 m/s Cut-In Speed (Feathered) Alternative, including implementation of the HCP and issuance of a 22-year ITP. The DEIS considers the direct, indirect, and cumulative effects of the alternatives, including any measures under the Proposed Action alternative intended to minimize and mitigate such impacts. The DEIS also identifies five additional alternatives that were considered but were eliminated from consideration (detailed in Section 3.1 of the DEIS).

The Service invites comments and suggestions from all interested parties on the content of the DEIS. In particular, information and comments regarding the following topics are requested:

1. The direct, indirect, or cumulative effects that implementation of any alternative could have on the human environment;
2. Whether or not the significance of the impact on various aspects of the human environment has been adequately analyzed; and
3. Any other information pertinent to evaluating the effects of the proposed action on the human environment.

Public Comments

You may submit your comments and materials concerning the notice by one of the methods listed in **ADDRESSES**. We request that you send comments only by one of the methods described in **ADDRESSES**.

If you submit a comment via *http://www.regulations.gov,* your entire comment—including any personal identifying information—will be posted on the Web site. We will post all hardcopy comments on *http://www.regulations.gov* as well. If you submit a hardcopy comment that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so.

Comments and materials we receive, as well as documents associated with the notice, will be available for public inspection on *http://www.regulations.gov* at Docket No. FWS–R3–ES–2013–0032, or by appointment, during normal business hours, at the Indiana Ecological Services Field Office in Bloomington, Indiana (see **FOR FURTHER INFORMATION CONTACT**).

Authority

We provide this notice under section 10(c) of the ESA (16 U.S.C. 1531 *et seq.*) and its implementing regulations (50 CFR 17.22), the NEPA (42 U.S.C. 4371 *et seq.*) and its implementing regulations (40 CFR 1506.6; 43 CFR part 46), and the NHPA (16 U.S.C. 470 *et seq.*) and its implementing regulations (36 CFR part 800).

Dated: March 20, 2013.

Lynn Lewis,

Assistant Regional Director, Ecological Services, Midwest Region.

[FR Doc. 2013–07595 Filed 4–4–13; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLWYP00000–L51100000–GA0000–LVEMK09CK350; WYW180711 and WYW173360]

Notice of Availability of Corrected Record of Decision for the Final Environmental Impact Statement for the South Gillette Area Maysdorf II Coal Lease by Application, WY

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Availability.

SUMMARY: In accordance with the National Environmental Policy Act of 1969, the Bureau of Land Management (BLM) announces the availability of a Correction to the Record of Decision (ROD) for the Maysdorf II Coal Lease-by-Application (LBA) included in the South Gillette Area Coal Lease Applications Final Environmental Impact Statement (EIS).

ADDRESSES: The document is available electronically on the following Web site: http://www.blm.gov/pgdata/content/wy/en/info/NEPA/documents/hpd/SouthGillette.html. Paper copies of the Correction to the ROD are also available at the following BLM office locations:

- Bureau of Land Management, Wyoming State Office, 5353 Yellowstone Road, Cheyenne, Wyoming, 82009; and
- Bureau of Land Management, Wyoming High Plains District Office, 2987 Prospector Drive, Casper, Wyoming, 82604.

FOR FURTHER INFORMATION CONTACT: Ms. Teresa Johnson, EIS Project Manager, at 307–261–7510. Ms. Johnson's office is located at the BLM Wyoming High Plains District Office, 2987 Prospector Drive, Casper, Wyoming 82604. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: This action corrects the inadvertently omitted wording and associated stipulations on page 19 in the Conformance With Existing Land Use Plans, and adds the inadvertently omitted Special Stipulations to page 32, Appendix 2, of the ROD sections of the Maysdorf II Record of Decision published in the **Federal Register** on Friday, August 30, 2012 (77 FR 52756). Both the original ROD and corrected ROD are available for review at http://www.blm.gov/pgdata/content/wy/en/info/NEPA/documents/hpd/SouthGillette.html.

This Corrected ROD is subject to appeal to the Interior Board of Land Appeals (IBLA), as provided in 43 CFR part 4, within thirty (30) days from the date of publication of this Notice of Availability in the **Federal Register**. The Corrected Record of Decision contains instructions for filing an appeal with the IBLA.

Mary J. Rugwell,

Associate State Director.

[FR Doc. 2013–07891 Filed 4–4–13; 8:45 am]

BILLING CODE 4310–22–P

DEPARTMENT OF JUSTICE

[OMB Number 1121–0329]

Agency Information Collection Activities; Proposed Collection; Comments Requested: Office of Justice Programs' Solicitation Template

ACTION: 60-Day Notice.

The Department of Justice (DOJ), Office of Justice Programs (OJP), has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (PRSA) of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for sixty days (60) until June 4, 2013. This process is conducted in accordance with 5 CFR 1320.10.

If you have additional comments on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact: Maria Swineford, (202) 616–0109, Office of Audit, Assessment, and Management, Office of Justice Programs, U.S. Department of Justice, 810 Seventh Street NW., Washington, DC 20531 or *maria.swineford@usdoj.gov.*

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
—Enhance the quality, utility, and clarity of the information to be collected; and
—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this Information

(1) *Type of Information Collection:* Renewal of a currently approved collection (1121–0329 and 1121–0188).

(2) *The Title of the Form/Collection:* OJP Solicitation Template

(3) *The Agency Form Number, if any, and the Applicable Component of the Department Sponsoring the Collection:* No form number available. Office of Justice Programs, Department of Justice.

(4) *Affected Public Who Will be Asked or Required to Respond, as well as a Brief Abstract:* The primary respondents are state agencies, tribal governments, local governments, colleges and universities, non-profit organizations, for-profit organizations, and faith-based organizations. The purpose of the solicitation template is to provide a framework to develop program-specific announcements soliciting applications for funding. A program solicitation outlines the specifics of the funding program; describes requirements for eligibility; instructs an applicant on the necessary components of an application under a specific program (e.g., project activities, project abstract, project timeline, proposed budget, etc.); outlines program evaluation and performance measures; explains selection criteria and the review process; and provides registration dates, deadlines, and instructions on how to apply within the designated application system. This collection is also incorporating the previously approved collection for the OJP Budget Detail Worksheet (1121–0188). The Budget Detail Worksheet is only required during the application process, and therefore should be included in this collection with the solicitation template, reducing the number of OMB PRA reviews and approvals needed. The primary respondents are the same, as listed above, and the worksheet

provides auto calculated fields and instructions for the necessary budget information required for each application submission (e.g. personnel/benefits, travel, indirect cost rates, etc.). The form is not mandatory and is recommended as guidance to assist the applicant in preparing their budget as authorized in 28 CFR part 66 and 28 CFR part 70.

(5) *An Estimate of the Total Number of Respondents and the Amount of Time Estimated for an Average Respondent to Respond:* It is estimated that information will be collected annually from approximately 10,000 applicants. Annual cost to the respondents is based on the number of hours involved in preparing and submitting a complete application package. Mandatory requirements for an application include a program narrative and budget details and narrative (formerly 1121–0188). Optional requirements can be imposed depending on the type of program to include, but not limited to: project abstract, indirect cost rate agreement, tribal authorizing resolution, timelines, logic models, memoranda of understanding, letters of support, resumes, disclosure of pending applications, and research and evaluation independence and integrity. Public reporting burden for this collection of information is estimated at up to 32 hours per application. The 32-hour estimate is based on the amount of time to prepare a research and evaluation proposal, one of the most time intensive types of application solicited by OJP. The estimate of burden hours is based on OJP's prior experience with the research application submission process.

(6) *An Estimate of the Total Public Burden (in hours) Associated with the collection:* The estimated public burden associated with this application is 320,000 hours.

If additional information is required contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., Room 3W–1407–B, Washington, DC 20530.

Dated: January 29, 2013.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2013–07963 Filed 4–4–13; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF JUSTICE

[OMB Number 1103–NEW]

Agency Information Collection Activities; Proposed New Collection; Comments Requested: COPS Survey on Police Consolidation and Shared Services

ACTION: 30-Day Notice.

The Department of Justice (DOJ) Office of Community Oriented Policing Services (COPS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** Volume 78, Number 23, page 7812, on February 4, 2013, allowing for a 60 day comment period.

The purpose of this notice is to allow for an additional 30 days for public comment until May 6, 2013. This process is conducted in accordance with 5 CFR 1320.10.

If you have comments, especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Danielle Ouellette, Department of Justice Office of Community Oriented Policing Services, 145 N Street, NE., Washington, DC 20530.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Enhance the quality, utility, and clarity of the information to be collected; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this Information Collection

(1) *Type of Information Collection:* Proposed new collection; comments requested.

(2) *Title of the Form/Collection:* COPS Survey on Police Consolidation and Shared Services.

(3) *Agency form number, if any, and the applicable component of the Department sponsoring the collection:* None. U.S. Department of Justice Office of Community Oriented Policing Services.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* In collaboration with the Michigan State University's School of Criminal Justice, the purpose of this one-time survey with is to conduct the first-ever census of public safety departments, which includes agencies that have at consolidated police and fire functions into a single organization. The survey will identify the nature, structure, function, organizational characteristics, and community policing activities of these departments. This information will be used to assess the implementation and variation of these departments, support a framework to advance further research on this type of agency and form of public safety delivery, and facilitate peer-to-peer information sharing.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* It is estimated that 135 respondents annually will complete the form within 1 hour.

(6) *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 135 total annual burden hours associated with this collection.

If additional information is required contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., Room 3W–1407, Washington, DC 20530.

Dated: April 4, 2013.

Jerri Murray,

Department Clearance Officer, PRA, U.S. Department of Justice.

[FR Doc. 2013–07964 Filed 4–4–13; 8:45 am]

BILLING CODE 4410–AT–P

DEPARTMENT OF JUSTICE

Office of Justice Programs

[OJP (NIJ) Docket No. 1621]

Walk-Through Metal Detectors and Hand-Held Metal Detectors Test Method Validation

AGENCY: National Institute of Justice, DOJ.

ACTION: Notice.

SUMMARY: National Institute of Justice has recently developed updated versions of its minimum performance standards for walk-through metal detectors and hand-held metal detectors. In order to ensure that the test methods in the standards are properly documented, NIJ is requesting proposals (including price quotes) for test method validation efforts from testing laboratories. NIJ is also seeking the participation of metal detector manufacturers in this effort to ensure that the test methods are valid and reasonable for metal detectors in the market today. Additional information for these efforts may be found through the National Law Enforcement and Corrections Technology Center's Web site by following the link below: *https://www.justnet.org/standards/Metal_Detectors.html*.

DATES: Please submit quotes or expressions of interest in participation by 5 p.m. Eastern Time on May 20, 2013.

FOR FURTHER INFORMATION CONTACT: David Otterson by telephone at (301) 519–5498 or by email at *david.m.otterson@lmco.com*.

Greg Ridgeway,

Acting Director, National Institute of Justice.

[FR Doc. 2013–07967 Filed 4–4–13; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of a Public Meeting of the Advisory Committee on Apprenticeship (ACA)

AGENCY: Employment and Training Administration (ETA), Labor.

ACTION: Notice of a public meeting.

SUMMARY: Pursuant to Section 10 of the Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2 § 10), notice is hereby given to announce a public meeting of the Advisory Committee on Apprenticeship (ACA) on June 5, 2013, and June 6, 2013. The ACA is a discretionary committee established by the Secretary of Labor, in accordance with FACA, as amended in 5 U.S.C. App. 2, and its implementing regulations (41CFR parts 101–6 and 102–3). All meetings of the ACA are open to the public.

DATES: The meeting will begin at approximately 9:30 a.m. Eastern Standard Time on Wednesday, June 5, 2013, and will continue until approximately 4:00 p.m. The meeting will reconvene on Thursday, June 6, 2013, at approximately 8:30 a.m. Eastern Standard Time and adjourn at approximately 4:00 p.m.

FOR FURTHER INFORMATION CONTACT: The Designated Federal Official, Mr. John V. Ladd, Administrator, Office of Apprenticeship, Employment and Training Administration, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–5311, Washington, DC 20210, Telephone: (202) 693–2796, (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: The first day of the meeting will take place at the Pentagon, Army Navy Drive and Fern Street, Arlington, Virginia, 22202 on June 5, 2013. The meeting will continue at the Department of Labor, Frances Perkins Building, 200 Constitution Avenue NW., Washington, DC, 20210, Executive Room, C5515 on the second day, June 6, 2013. Members of the public are encouraged to arrive early to allow for security clearance into the building at both the Pentagon and the Francis Perkins Building.

Security Instructions for June 5, 2013 at the Pentagon:

In order to ensure everyone's safety, these guidelines must be followed when visiting the Pentagon. There are no exceptions to these rules and non-compliance will result in the inability to attend the meeting.

1. Arrive 30 minutes before the ACA meeting to allow time for processing through building security. Meeting participants will need to be checked in prior to the scheduled meeting time.

2. There is no *public parking* at the Pentagon. Public parking is available at the Pentagon City mall. It is also highly encouraged to use the Metro rail.

3. All purses, bags/briefcases carried into the Pentagon are subject to search. The following items are *prohibited* inside the building: Weapons of any sort (i.e., knives, box cutters, mace, pepper spray, etc.) that may cause bodily harm and large bags (i.e., knapsacks, camera bags, backpacks and shopping bags, etc). Anyone with the mentioned items will not be allowed on tour with such items.

The following items are not prohibited inside the building, but cannot be used along the tour route:

4. Electronic devices (i.e., cell phones, picture or video cameras, PDAs, blackberries, laptops, etc.) and tobacco products. You are encouraged to leave these items in the hotel, bus or van, or at home as it will slow down the processing into the building.

5. Proper Identification (ID) must be shown to building security. Ages 18 and up—require 2 forms of ID (one form must be a photo ID, the other may be a credit/debit card, social security card, birth certificate, or another item with the individual's name printed on it [excluding business cards]).

6. Please contact Pentagon Force Protection Agency directly at (703) 697–1001 regarding acceptable forms of ID.

7. Meeting participants not checked in *inside the Pentagon Visitors Center* by the scheduled meeting time will not be allowed to attend the meeting.

8. There is *no photography* allowed inside and outside of the Pentagon.

9. Meeting participants must stay to the center of the corridor to allow Pentagon personnel to pass by on either side and must stay together.

10. Food and beverages are *not* permitted into the meeting.

Any violation of these security measures will cause the tour to be terminated.

Security Instructions for June 6, 2013 at the Frances Perkins Building

Meeting participants should use the visitor's entrance to access Frances Perkins Building, one block north of Constitution Avenue on at 3rd and C Streets NW. For security purposes meeting participants must:

1. Present a valid photo ID to receive a visitor badge.

2. Know the name of the event you are attending: the meeting event is the Advisory Committee on Apprenticeship.

3. Visitor badges are issued by the security officer at the Visitor Entrance located at 3rd and C Streets NW. When you receive your visitor badge, the security officer will retain your photo ID until you return the visitor badge.

4. Laptops and other electronic devices may be inspected and logged for identification purposes.

5. Due to limited parking options, Metro rail is the easiest way to access the Frances Perkins Building.

Notice of Intent To Attend the Meeting

All meeting participants are being asked to submit a notice of intent to attend by Wednesday, May 1, 2013, via email to Mr. John V. Ladd at *oa.administrator@dol.gov,* subject line

''June 2013 ACA Meeting.'' Please indicate if you will be attending both days at both locations. This information is necessary to provide adequate space to accommodate all meeting participants. If individuals have special needs and/or disabilities that will require special accommodations, please contact Kenya Huckaby on (202) 693–3795 or via email at *Huckaby.kenya@dol.gov* no later than Wednesday, May 15, 2013. Any member of the public who wishes to file written data or comments pertaining to the agenda may do so by sending the data or comments to Mr. John V. Ladd via email at *oa.administrator@dol.gov,* subject line ''June 2013 ACA Meeting,'' or submitting to the Office of Apprenticeship, Employment and Training Administration, U.S. Department of Labor, Room N–5311, 200 Constitution Avenue NW., Washington, DC 20210. Such submissions will be included in the record for the meeting if received by Wednesday, May 15, 2013.

Purpose of the Meeting and Topics To Be Discussed

The primary purpose of the meeting is to discuss strategies to increase opportunities for transitioning veterans into Registered Apprenticeship and consider possible workgroups for the upcoming year. The meeting agenda will include the following:

- Brainstorming and Open Discussion on 4 Key Veteran Focused Issues Related to Registered Apprenticeship;
- German Skills Initiative;
- Sector Caucus Breakouts Sessions;
- Office of Apprenticeship Updates;
- ACA Workgroup Formation;
- Aspen Institute Report on Apprenticeship Cancelation Rates;
- Other Matters of Interest to the Registered Apprenticeship Community
- Public Comment

The agenda may be updated should priority items come before the ACA between the time of this publication and the scheduled date of the ACA meeting. All meeting updates will be posted to the Office of Apprenticeship's homepage: *http://www.doleta.gov/oa/.* Any member of the public who wishes to speak at the meeting should indicate the nature of the intended presentation and the amount of time needed by furnishing a written statement to the Designated Federal Official, Mr. John V. Ladd, by Wednesday, May 22, 2013. The Chairperson will announce at the beginning of the meeting the extent to which time will permit the granting of such requests.

Signed at Washington, DC, this 25th day of March 2013.

Jane Oates,

Assistant Secretary for the Employment and Training Administration.

[FR Doc. 2013–07918 Filed 4–4–13; 8:45 am]

BILLING CODE 4510–FR–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: 13–043]

NASA Advisory Council; Audit, Finance and Analysis Committee; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of Meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92–463, as amended, the National Aeronautics and Space Administration announces a meeting of the Audit, Finance and Analysis Committee of the NASA Advisory Council.

DATES: Monday, April 22, 2013, 9:00 a.m.–4:30 p.m., and Tuesday, April 23, 2013 9:00 a.m.–10:00 a.m., Local Time.

ADDRESSES: NASA Headquarters, 300 E Street, SW., Room 8E40, Washington, DC 20456.

FOR FURTHER INFORMATION CONTACT: Ms. Charlene Williams, Office of the Chief Financial Officer, National Aeronautics and Space Administration Headquarters, Washington, DC 20546. Phone: 202–358–2183, fax: 202–358–4336.

SUPPLEMENTARY INFORMATION: The agenda for the meeting includes the following topics

- Finance/Budget Updates.
- Conference Cost Reporting Requirements.
- Financial Statement Audit Update.
- Unfunded Environmental Liabilities.
- Internal Control Assurances.

The meeting will be open to the public up to the seating capacity of the room. It is imperative that the meeting be held on this date to accommodate the scheduling priorities of the key participants. Attendees will be requested to sign a register and comply with NASA Security requirements, including presentation of a valid picture ID to Security before access to NASA Headquarters. Foreign nationals attending this meeting will be required to provide no less than 10 working days prior to the meeting: Full name, gender; date/place of birth; citizenship; visa information (number, type, expiration date); passport information (number, country, expiration date); employer/affiliation information (name of institution, address, country, telephone); title/position of attendee; and home address to Ms. Charlene Williams at fax number 202–358–4336. U.S. Citizens and Permanent Residents (green card holders) are requested to submit their name and affiliation 3 working days prior to the meeting to Ms. Charlene Williams via email at *charlene.williams-1@nasa.gov* or by telephone at 202–358–2183 or fax at 202–358–4336.

Patricia D. Rausch,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 2013–07996 Filed 4–4–13; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: 13–042]

NASA Advisory Council; Human Exploration and Operations Committee; Research Subcommittee; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92–462, as amended, the National Aeronautics and Space Administration (NASA) announces a meeting of the Research Subcommittee of the Human Exploration and Operations Committee (HEOC) of the NASA Advisory Council (NAC). This Subcommittee reports to the HEOC. The meeting will be held for the purpose of organizing the activities of the Subcommittee and fact-finding with respect to the research activities within the Human Exploration and Operations Mission Directorate.

DATES: 10:00 a.m.–1:00 p.m., April 17, 2013, Local Time.

FOR FURTHER INFORMATION CONTACT: Dr. Bradley Carpenter, Human Exploration and Operations Mission Directorate, NASA Headquarters, Washington, DC 20546, (202) 358–0826, or *bcarpenter@nasa.gov,* Human Exploration and Operations Mission Directorate, NASA Headquarters, Washington, DC 20546.

SUPPLEMENTARY INFORMATION: This meeting will be held telephonically and by WebEx. Any interested person may call the USA toll free conference call number 866–784–1921, passcode 8715266 or toll number 203–310–8326,

to participate in this meeting by telephone. The WebEx link is *https://nasa.webex.com/,* the meeting number is 997 730 108, and the passcode is @pril172013.

Publication with less than 15 calendar day notice due to sequestration requirements.

The agenda for the meeting includes the following topics:

—Overview of Research in Space Life and Physical Sciences
—Space Station and Future Exploration Missions
—Discussion on Priorities and Tasking for the Subcommittee

It is imperative that the meeting be held on these dates to accommodate the scheduling priorities of the key participants.

Patricia D. Rausch,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 2013–07995 Filed 4–4–13; 8:45 am]

BILLING CODE 7510–13–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2013–43 and CP2013–56; Order No. 1686]

New Competitive Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning an addition to the competitive product list. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: Comments are due: April 8, 2013.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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II. Notice of Filings
III. Ordering Paragraphs

I. Introduction

In accordance with 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.,* the Postal Service filed a formal request and associated supporting information to add Priority Mail Contract 57 to the competitive product list.[1] It asserts that Priority Mail Contract 57 is a competitive product ''not of general applicability'' within the meaning of 39 U.S.C. 3632(b)(3). Request at 1. The Request has been assigned Docket No. MC2013–43.

The Postal Service contemporaneously filed a redacted contract related to the proposed new product under 39 U.S.C. 3632(b)(3) and 39 CFR 3015.5. *Id.* Attachment B. The instant contract has been assigned Docket No. CP2013–56.

Request. To support its Request, the Postal Service filed six attachments as follows:

- Attachment A—a redacted copy of Governors' Decision No. 11–6, authorizing the new product;
- Attachment B—a redacted copy of the contract;
- Attachment C—proposed changes to the Mail Classification Schedule competitive product list with the addition underlined;
- Attachment D—a Statement of Supporting Justification as required by 39 CFR 3020.32;
- Attachment E—a certification of compliance with 39 U.S.C. 3633(a); and
- Attachment F—an application for non-public treatment of materials to maintain redacted portions of the contract and related financial information under seal.

In the Statement of Supporting Justification, Dennis R. Nicoski, Manager, Field Sales Strategy and Contracts, asserts that the contract will cover its attributable costs, make a positive contribution to covering institutional costs, and increase contribution toward the requisite 5.5 percent of the Postal Service's total institutional costs. *Id.* Attachment D at 1. Mr. Nicoski contends that there will be no issue of market dominant products subsidizing competitive products as a result of this contract. *Id.*

Related contract. The Postal Service included a redacted version of the related contract with the Request. *Id.* Attachment B. The contract is scheduled to become effective 1 business day after the day on which the Commission issues all necessary regulatory approval. *Id.* at 2. The contract will expire 3 years from the effective date unless, among other things, either party terminates the agreement upon 30 days' written notice to the other party. *Id.* at 3. The Postal Service represents that the contract is consistent with 39 U.S.C. 3633(a). *Id.* Attachment E.

The Postal Service filed much of the supporting materials, including the related contract, under seal. *Id.* Attachment F. It maintains that the redacted portions of the Governors' Decision, contract, customer-identifying information, and related financial information, should remain confidential. *Id.* at 3. This information includes the price structure, underlying costs and assumptions, pricing formulas, information relevant to the customer's mailing profile, and cost coverage projections. *Id.* The Postal Service asks the Commission to protect customer-identifying information from public disclosure indefinitely. *Id.* at 7.

II. Notice of Filings

The Commission establishes Docket Nos. MC2013–43 and CP2013–56 to consider the Request pertaining to the proposed Priority Mail Contract 57 product and the related contract, respectively.

Interested persons may submit comments on whether the Postal Service's filings in the captioned dockets are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642, 39 CFR 3015.5, and 39 CFR part 3020, subpart B. Comments are due no later than April 8, 2013. The public portions of these filings can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Pamela A. Thompson to serve as Public Representative in these dockets.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket Nos. MC2013–43 and CP2013–56 to consider the matters raised in each docket.

2. Pursuant to 39 U.S.C. 505, Pamela A. Thompson is appointed to serve as an officer of the Commission (Public Representative) to represent the interests of the general public in these proceedings.

3. Comments by interested persons in these proceedings are due no later than April 8, 2013.

4. The Secretary shall arrange for publication of this order in the **Federal Register.**

By the Commission.

Shoshana M. Grove,

Secretary.

[FR Doc. 2013–07913 Filed 4–4–13; 8:45 am]

BILLING CODE 7710–FW–P

[1] Request of the United States Postal Service to Add Priority Mail Contract 57 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data, March 28, 2013 (Request).

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 17a–8, OMB Control No. 3235–0235, SEC File No. 270–225.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), the Securities and Exchange Commission (the ''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for extension of the previously approved collection of information discussed below.

Rule 17a–8 (17 CFR 270.17a–8) under the Investment Company Act of 1940 (the ''Act'') (15 U.S.C. 80a) is entitled ''Mergers of affiliated companies.'' Rule 17a–8 exempts certain mergers and similar business combinations (''mergers'') of affiliated registered investment companies (''funds'') from prohibitions under section 17(a) of the Act (15 U.S.C. 80a–17(a)) on purchases and sales between a fund and its affiliates. The rule requires fund directors to consider certain issues and to record their findings in board minutes. The rule requires the directors of any fund merging with an unregistered entity to approve procedures for the valuation of assets received from that entity. These procedures must provide for the preparation of a report by an independent evaluator that sets forth the fair value of each such asset for which market quotations are not readily available. The rule also requires a fund being acquired to obtain approval of the merger transaction by a majority of its outstanding voting securities, except in certain situations, and requires any surviving fund to preserve written records describing the merger and its terms for six years after the merger (the first two in an easily accessible place).

The average annual burden of meeting the requirements of rule 17a–8 is estimated to be 7 hours for each fund. The Commission staff estimates that each year approximately 736 funds rely on the rule. The estimated total average annual burden for all respondents therefore is 5,152 hours.

This estimate represents an increase of 882 hours from the prior estimate of 4,270 hours. This increase reflects a change in the estimated number of funds relying on rule 17a–8.

The average cost burden of preparing a report by an independent evaluator in a merger with an unregistered entity is estimated to be $15,000. The average net cost burden of obtaining approval of a merger transaction by a majority of a fund's outstanding voting securities is estimated to be $100,000. The Commission staff estimates that each year approximately 0 mergers with unregistered entities occur and approximately 15 funds hold shareholder votes that would not otherwise have held a shareholder vote. The total annual cost burden of meeting these requirements is estimated to be $1,500,000.

The estimates of average burden hours and average cost burdens are made solely for the purposes of the Paperwork Reduction Act, and are not derived from a comprehensive or even a representative survey or study. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The public may view the background documentation for this information collection at the following Web site, www.reginfo.gov. Comments should be directed to: (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 by sending an email to: *Shagufta_Ahmed@omb.eop.gov;* and (ii) Thomas Bayer, Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 6432 General Green Way, Alexandria, VA 22312 or send an email to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: April 1, 2013.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–07945 Filed 4–4–13; 8:45 am]

BILLING CODE 8011–01–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 248.30, OMB Control No. 3235–0610, SEC File No. 270–549.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (the ''Commission'') has submitted to the Office of Management and Budget a request for extension of the previously approved collection of information discussed below.

Rule 248.30 (17 CFR 248.30) under Regulation S–P, is titled ''Procedures to Safeguard Customer Records and Information; Disposal of Consumer Report Information.'' Rule 248.30 (the ''safeguard rule'') requires brokers, dealers, investment companies, and investment advisers registered with the Commission (''registered investment advisers'') (collectively ''covered institutions'') to adopt written policies and procedures for administrative, technical, and physical safeguards to protect customer records and information. The safeguards must be reasonably designed to ''insure the security and confidentiality of customer records and information,'' ''protect against any anticipated threats or hazards to the security and integrity'' of those records, and protect against unauthorized access to or use of those records or information, which ''could result in substantial harm or inconvenience to any customer.'' The safeguard rule's requirement that covered institutions' policies and procedures be documented in writing constitutes a collection of information and must be maintained on an ongoing basis. This requirement eliminates uncertainty as to required employee actions to protect customer records and information and promotes more systematic and organized reviews of safeguard policies and procedures by institutions. The information collection also assists the Commission's examination staff in assessing the existence and adequacy of covered institutions' safeguard policies and procedures.

We estimate that as of the end of 2011, there are 4695 broker-dealers, 4203 investment companies, and 11,658 investment advisers currently registered with the Commission, for a total of 20,556 covered institutions. We believe that all of these covered institutions have already documented their safeguard policies and procedures in writing and therefore will incur no hourly burdens related to the initial documentation of policies and procedures.

Although existing covered institutions would not incur any initial hourly burden in complying with the safeguards rule, we expect that newly registered institutions would incur some

hourly burdens associated with documenting their safeguard policies and procedures. We estimate that approximately 1500 broker-dealers, investment companies, or investment advisers register with the Commission annually. However, we also expect that approximately 70% of these newly registered covered institutions (1050) are affiliated with an existing covered institution, and will rely on an organization-wide set of previously documented safeguard policies and procedures created by their affiliates. We estimate that these affiliated newly registered covered institutions will incur a significantly reduced hourly burden in complying with the safeguards rule, as they will need only to review their affiliate's existing policies and procedures, and identify and adopt the relevant policies for their business. Therefore, we expect that newly registered covered institutions with existing affiliates will incur an hourly burden of approximately 15 hours in identifying and adopting safeguard policies and procedures for their business, for a total hourly burden for all affiliated new institutions of 15,750 hours.

Finally, we expect that the 450 newly registered entities that are not affiliated with an existing institution will incur a significantly higher hourly burden in reviewing and documenting their safeguard policies and procedures. We expect that virtually all of the newly registered covered entities that do not have an affiliate are likely to be small entities and are likely to have smaller and less complex operations, with a correspondingly smaller set of safeguard policies and procedures to document, compared to other larger existing institutions with multiple affiliates. We estimate that it will take a typical newly registered unaffiliated institution approximately 60 hours to review, identify, and document their safeguard policies and procedures, for a total of 27,000 hours for all newly registered unaffiliated entities.

Therefore, we estimate that the total annual hourly burden associated with the safeguards rule is 42,750 hours. We also estimate that all covered institutions will be respondents each year, for a total of 20,556 respondents.

These estimates of average burden hours are made solely for the purposes of the Paperwork Reduction Act. 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. The safeguard rule does not require the reporting of any information or the filing of any documents with the Commission. The collection of information required by the safeguard rule is mandatory.

The public may view the background documentation for this information collection at the following Web site, *www.reginfo.gov.* Comments should be directed to: (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 by sending an email to: *Shagufta_Ahmed@omb.eop.gov;* and (ii) Thomas Bayer, Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 6432 General Green Way, Alexandria, VA 22312 or send an email to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: April 1, 2013.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–07944 Filed 4–4–13; 8:45 am]

BILLING CODE 8011–01–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 607, OMB Control No. 3235–0634; SEC File No. 270–561.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (the ''Commission'') has submitted to the Office of Management and Budget a request for extension of the previously approved collection of information discussed below.

Regulation E (17 CFR 230.601–230.610a) exempts from registration under the Securities Act of 1933 (15 U.S.C. 77a et seq.) (''Securities Act'') securities issued by a small business investment company (''SBIC'') which is registered under the Investment Company Act of 1940 (15 U.S.C. 80a–1 et seq.) (''Investment Company Act'') or a closed-end investment company that has elected to be regulated as a business development company (''BDC'') under the Investment Company Act, so long as the aggregate offering price of all securities of the issuer that may be sold within a 12-month period does not exceed $5,000,000 and certain other conditions are met. Rule 607 under Regulation E (17 CFR 230.607) entitled, ''Sales material to be filed,'' requires sales material used in connection with securities offerings under Regulation E to be filed with the Commission at least five days (excluding weekends and holidays) prior to its use.[1] Commission staff reviews sales material filed under rule 607 for materially misleading statements and omissions. The requirements of rule 607 are designed to protect investors from the use of false or misleading sales material in connection with Regulation E offerings.

Respondents to this collection of information include SBICs and BDCs making an offering of securities under Regulation E. Each respondent's reporting burden under rule 607 relates to the burden associated with filing its sales material electronically. The burden of filing electronically, however, is negligible and there have been no filings made under this rule, so this collection of information does not impose any burden on the industry. However, we are requesting one annual response and an annual burden of one hour for administrative purposes. The estimate of average burden hours is made solely for purposes of the Paperwork Reduction Act and is not derived from a quantitative, comprehensive, or even representative survey or study of the burdens associated with Commission rules and forms.

The requirements of this collection of information are mandatory. Responses will not be kept confidential. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid control number.

The public may view the background documentation for this information collection at the following Web site, *www.reginfo.gov.* Comments should be directed to: (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 by sending an email to: *Shagufta_Ahmed@omb.eop.gov;* and (ii) Thomas Bayer, Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon,

[1] Sales material includes advertisements, articles or other communications to be published in newspapers, magazines, or other periodicals; radio and television scripts; and letters, circulars or other written communications proposed to be sent given or otherwise communicated to more than ten persons.

6432 General Green Way, Alexandria, VA 22312 or send an email to: *PRA_Mailbox@sec.gov*. Comments must be submitted to OMB within 30 days of this notice.

Dated: April 1, 2013.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–07943 Filed 4–4–13; 8:45 am]

BILLING CODE 8011–01–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:

Form N–8F, OMB Control No. 3235–0157; SEC File No. 270–136.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (the ''Commission'') has submitted to the Office of Management and Budget a request for extension of the previously approved collection of information discussed below.

Form N–8F (17 CFR 274.218) is the form prescribed for use by registered investment companies in certain circumstances to request orders of the Commission declaring that the registration of that investment company cease to be in effect. The form requests information about: (i) The investment company's identity, (ii) the investment company's distributions, (iii) the investment company's assets and liabilities, (iv) the events leading to the request to deregister, and (v) the conclusion of the investment company's business. The information is needed by the Commission to determine whether an order of deregistration is appropriate.

The Form takes approximately 5.5 hours on average to complete. It is estimated that approximately 142 investment companies file Form N–8F annually, so the total annual burden for the form is estimated to be approximately 781 hours. The estimate of average burden hours is made solely for the purposes of the Paperwork Reduction Act and is not derived from a comprehensive or even a representative survey or study.

The collection of information on Form N–8F is not mandatory. The information provided on Form N–8F is not kept confidential. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently-valid OMB control number.

The public may view the background documentation for this information collection at the following Web site: www.reginfo.gov. Comments should be directed to: (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 by sending an email to: Shagufta_Ahmed@omb.eop.gov; and (ii) Thomas Bayer, Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 6432 General Green Way, Alexandria, VA 22312 or by sending an email to: PRA_Mailbox@sec.gov. Comments must be submitted to OMB within 30 days of this notice.

Dated: April 1, 2013.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–07942 Filed 4–4–13; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. IC–30440]

Notice of Applications for Deregistration Under Section 8(f) of the Investment Company Act of 1940

March 29, 2013.

The following is a notice of applications for deregistration under section 8(f) of the Investment Company Act of 1940 for the month of March 2013. A copy of each application may be obtained via the Commission's Web site by searching for the file number, or for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090. An order granting each application will be issued unless the SEC orders a hearing. Interested persons may request a hearing on any application by writing to the SEC's Secretary at the address below and serving the relevant applicant with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on April 23, 2013, and should be accompanied by proof of service on the applicant, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

FOR FURTHER INFORMATION CONTACT: Diane L. Titus at (202) 551–6810, SEC, Division of Investment Management, Exemptive Applications Office, 100 F Street NE., Washington, DC 20549–8010.

Highland Floating Rate Fund [File No. 811–8953]

Highland Floating Rate Advantage Fund [File No. 811–9709]

Summary: Each applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. Applicants have transferred their assets to a series of Pyxis Funds I, and on June 13, 2011, each applicant made a final distribution to its shareholders based on net asset value. Expenses of approximately $275,832 and $365,637, respectively, incurred in connection with the reorganizations were paid by each applicant.

Filing Dates: The applications were filed on October 12, 2012, and amended on January 24, 2013.

Applicant's Address: 300 Crescent Ct., Suite 700, Dallas, TX 75201.

Highland Event Driven Fund [File No. 811–22101]

Highland/U.S. Global Infrastructure Fund [File No. 811–22226]

Summary: Each applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. Applicants have never made public offerings of their securities and do not propose to make public offerings or engage in business of any kind.

Filing Dates: The applications were filed on October 10, 2012, and amended on January 24, 2013.

Applicants' Address: 300 Crescent Ct., Suite 700, Dallas, TX 75201.

Legg Mason Investment Trust Inc. [File No. 811–9613]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. Applicant has transferred its assets to a corresponding shell series of Legg Mason Investment Trust, and on April 30, 2012, applicant made a final distribution to its shareholders based on net asset value. Expenses of approximately $38,567 incurred in connection with the reorganization were paid by applicant.

Filing Dates: The application was filed on February 5, 2013, and amended on March 1, 2013.

Applicant's Address: 100 International Dr., 7th Floor, Baltimore, MD 21202.

BlackRock Credit Allocation Income Trust II, Inc. [File No. 811–21286]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. The applicant has transferred its assets to BlackRock Credit Allocation Income Trust IV and, on December 10, 2012, made a final distribution to its shareholders based on net asset value. Expenses of $340,672 incurred in connection with the reorganization were paid by BlackRock Advisors, LLC, applicant's investment adviser.

Filing Dates: The application was filed on January 15, 2013, and amended on February 21, 2013 and March 25, 2013.

Applicant's Address: 100 Bellevue Parkway, Wilmington, DE 19809.

Excelsior Multi-Strategy Hedge Fund of Funds (TE), LLC [File No. 811–22035]

Excelsior Multi-Strategy Hedge Fund of Funds (TI), LLC [File No. 811–22036]

Excelsior Multi-Strategy Hedge Fund of Funds (TE 2), LLC [File No. 811–22318]

Summary: Each applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. The applicants have transferred their assets to Excelsior Multi-Strategy Hedge Fund of Funds, LLC (formerly named Excelsior Multi-Strategy Hedge Fund of Funds Master Fund, LLC) and, on December 31, 2012, Excelsior Multi-Strategy Hedge Fund of Funds (TE), LLC and Excelsior Multi-Strategy Hedge Fund of Funds (TI), LLC, and on January 31, 2013, Excelsior Multi-Strategy Hedge Fund of Funds (TE2), LLC, each made a final distribution to its shareholders based on net asset value. Each applicant incurred expenses of approximately $75,000 in connection with its reorganization.

Filing Date: The applications were filed on February 21, 2013.

Applicant's Address: 225 High Ridge Rd., Stamford, CT 06905.

Eclipse Funds [File No. 811–4847]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. Each series of applicant has transferred its assets to a corresponding shell series of MainStay Funds Trust and, on May 25, 2012, made a final distribution to its shareholders based on net asset value. Expenses of $142,330 incurred in connection with the reorganization were paid by applicant.

Filing Date: The application was filed on February 8, 2013.

Applicant's Address: 51 Madison Ave., New York, NY 10010.

NCM Capital Investment Trust [File No. 811–22015]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On August 30, 2012, applicant made a liquidating distribution to its shareholders, based on net asset value. Expenses of $13,793 incurred in connection with the liquidation were paid by NCM Capital Advisers, Inc., applicant's investment adviser.

Filing Date: The application was filed on February 22, 2013.

Applicant's Address: 2634 Durham-Chapel Hill Boulevard, Suite 206, Durham, NC 27707.

DWS Value Equity Trust [File No. 811–1444]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. Applicant has transferred its assets to DWS S&P 500 Index Fund, a series of DWS Institutional Funds, and on April 30, 2012, applicant made a final distribution to its shareholders based on net asset value. Expenses of $185,690 incurred in connection with the reorganization were paid by Deutsche Investment Management Americas Inc., applicant's investment adviser.

Filing Date: The application was filed on February 22, 2013.

Applicant's Address: 345 Park Ave., New York, NY 10154.

Midas Perpetual Portfolio, Inc. [File No. 811–2474]

Midas Magic, Inc. [File No. 811–4625]

Summary: Each applicant seeks an order declaring that it has ceased to be an investment company. The applicants have transferred their assets to Midas Series Trust and, on October 12, 2012, each made a final distribution to its shareholders based on net asset value. Expenses of approximately $79,092 and $79,487, respectively, incurred in connection with the reorganizations were paid by each applicant.

Filing Date: The applications were filed on March 4, 2013.

Applicant's Address: 11 Hanover Sq., New York, NY 10005.

FBR Funds [File No. 811–21503]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. Each series of applicant has transferred its assets to a corresponding series of Hennessy Funds Trust or Hennessy Mutual Funds, Inc. and, on October 26, 2012, made a final distribution to its shareholders based on net asset value. Expenses of $1,175,000 incurred in connection with the reorganization were paid by FBR Fund Advisers, Inc., applicant's investment adviser, and Hennessy Advisors, Inc., investment adviser to the acquiring funds.

Filing Date: The application was filed on March 1, 2013.

Applicant's Address: FBR Fund Advisers, Inc., 1001 Nineteenth St. North, Arlington, VA 22209.

YieldQuest Funds Trust [File No. 811–21771]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On August 31, 2012, applicant made a liquidating distribution to its shareholders, based on net asset value. Expenses of $31,250 incurred in connection with the liquidation were paid by applicant and YieldQuest Advisors, LLC, applicant's investment adviser.

Filing Date: The application was filed on February 22, 2013.

Applicant's Address: 3280 Peachtree Rd., Suite 2600, Atlanta, GA 30305.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–07946 Filed 4–4–13; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 30441; File No. 812–14099]

Munder Series Trust, *et al.;* Notice of Application

March 29, 2013.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice of an application under section 6(c) of the Investment Company Act of 1940 (''Act'') for an exemption from section 15(a) of the Act and rule 18f–2 under the Act, as well as from certain disclosure requirements.

SUMMARY: *Summary of Application:* Applicants request an order that would permit them to enter into and materially amend sub-advisory agreements with Wholly-Owned Sub-Advisers (as defined below) and non-affiliated sub-advisers without shareholder approval and would grant relief from certain disclosure requirements.

Applicants: Munder Series Trust (the ''Trust'') and Munder Capital Management (''MCM'').

DATES: *Filing Dates:* The application was filed on November 28, 2012, and amended on December 31, 2012, March 15, 2013 and March 28, 2013.

Hearing or Notification of Hearing: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on April 23, 2013, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Elizabeth M. Murphy, Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090. Applicants, 480 Pierce Street, Birmingham, MI 48009.

FOR FURTHER INFORMATION CONTACT: Bruce R. MacNeil, Senior Counsel, at (202) 551–6876, or Daniele Marchesani, Branch Chief, at (202) 551–6821 (Division of Investment Management, Exemptive Applications Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number or an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Applicants' Representations

1. The Trust is organized as a Delaware statutory trust and is registered under the Act as an open-end management investment company. The Trust may offer one or more series of shares (each, a ''Series'') with its own distinct investment objective, policies and restrictions.[1] MCM is organized as a Delaware general partnership and is registered as an investment adviser under the Investment Advisers Act of 1940 (''Advisers Act''). Each Series has, or will have, as its investment adviser, MCM, or another investment adviser controlling, controlled by or under common control with MCM or its successors (each, an ''Adviser'').[2] Any future Adviser will also be registered as an investment adviser under the Advisers Act.[3]

2. The Adviser serves as the investment adviser to each Series pursuant to an investment advisory agreement with the Trust (''Investment Advisory Agreement''). The Investment Advisory Agreement was approved by the board of trustees of the Trust (''Board''),[4] including a majority of the members of the Board who are not ''interested persons,'' as defined in section 2(a)(19) of the Act, of the Trust, of a Series or the Adviser (''Independent Trustees'') and by the shareholders of the relevant Series as required by sections 15(a) and 15(c) of the Act and rule 18f-2 thereunder. The terms of the Investment Advisory Agreement comply with section 15(a) of the Act.

3. Under the terms of the Investment Advisory Agreement, the Adviser, subject to the supervision of the Board, will provide continuous investment management of the assets of each Series. The Adviser periodically reviews each Series' investment objective, policies and strategies, and based on the need of a Series may recommend changes to the investment objective, policies and strategies of the Series for consideration by the Board. For its services to each Series under the Investment Advisory Agreement, the Adviser receives an advisory fee from that Series based on the average daily net assets of that Series. The Investment Advisory Agreement provides that the Adviser may, subject to the approval of the Board, including a majority of the Independent Trustees, and the shareholders of the applicable Series (if required), delegate portfolio management responsibilities of all or a portion of the assets of a Series to a Sub-Adviser.[5]

4. Applicants request an order to permit the Adviser, subject to the approval of the Board, including a majority of the Independent Trustees, to, without obtaining shareholder approval: (a) Select Sub-Advisers to manage all or a portion of the assets of a Series and enter into Sub-Advisory Agreements (as defined below) with the Sub-Advisers, and (b) materially amend Sub-Advisory Agreements with the Sub-Advisers.[6] The requested relief will not extend to any sub-adviser, other than a Wholly-Owned Sub-Adviser, who is an affiliated person, as defined in section 2(a)(3) of the Act, of the Sub-Advised Series, of the Trust, or of the Adviser, other than by reason of serving as a sub-adviser to one or more of the Sub-Advised Series (''Affiliated Sub-Adviser'').

5. Pursuant to the terms of the Investment Advisory Agreement, the Adviser will have overall responsibility for the management and investment of each Series' assets. These responsibilities include recommending the removal or replacement of Sub-Advisers, determining the portion of that Sub-Advised Series' assets to be managed by any given Sub-Adviser and reallocating those assets as necessary from time to time.

6. The Adviser has entered into sub-advisory agreements with various Sub-Advisers (''Sub-Advisory Agreements'') to provide investment management services to the Sub-Advised Series.[7] The terms of the Sub-Advisory Agreements comply fully with the requirements of

[1] The current Series of the Trust are: Munder Bond Fund, Munder Growth Opportunities Fund, Munder Index 500 Fund, Munder Integrity Mid-Cap Value Fund, Munder Integrity Small/Mid-Cap Value Fund, Munder International Fund-Core Equity, Munder International Small-Cap Fund, Munder Large-Cap Value Fund, Munder Micro-Cap Equity Fund, Munder Mid-Cap Core Growth Fund, and Munder Veracity Small-Cap Value Fund.

[2] For purposes of the requested order, ''successor'' is limited to an entity that results from a reorganization into another jurisdiction or a change in the type of business organization.

[3] Applicants request that the relief apply to applicants, as well as to any future Series and any other existing or future registered open-end management investment company or series thereof that (a) is advised by an Adviser, (b) uses the manager of managers structure described in the application (''Manager of Managers Structure''), and (c) complies with the terms and conditions of the application (''Sub-Advised Series''). All registered open-end investment companies that currently intend to rely on the requested order are named as applicants. Any entity that relies on the requested order will do so only in accordance with the terms and conditions contained in the application.

[4] The term ''Board'' also includes the board of trustees or directors of a future Series.

[5] As used herein, a ''Sub-Adviser'' is (a) an indirect or direct ''wholly-owned subsidiary'' (as such term is defined in the Act) of the Adviser for that Series; (b) a sister company of the Adviser for that Series that is an indirect or direct ''wholly-owned subsidiary'' (as such term is defined in the Act) of the same company that, indirectly or directly, wholly owns the Adviser (each of (a) and (b), a ''Wholly-Owned Sub-Adviser'' and collectively, the ''Wholly-Owned Sub-Advisers''), or (c) not an ''affiliated person'' (as such term is defined in section 2(a)(3) of the Act) of the applicable Series, the Trust, or the Adviser, except to the extent that an affiliation arises solely because the Sub-adviser serves as a sub-adviser to a Series (each, a ''Non-Affiliated Sub-Adviser'').

[6] Shareholder approval will continue to be required for any other sub-adviser change (not otherwise permitted by rule or other action of the Commission or staff) and material amendments to an existing Sub-Advisory Agreement with any sub-adviser other than a Non-Affiliated Sub-Adviser or a Wholly-Owned Sub-Adviser (all such changes referred to as ''Ineligible Sub-Adviser Changes'').

[7] If the name of any Sub-Advised Series contains the name of a Sub-Adviser, the name of the Adviser that serves as the primary adviser to the Sub-Advised Series, or a trademark or trade name that is owned by that Adviser, will precede the name of the Sub-Adviser.

section 15(a) of the Act and were approved by the Board, including a majority of the Independent Trustees and the shareholders of the applicable Series, in accordance with sections 15(a) and 15(c) of the Act and rule 18f-2 thereunder. The specific day-to-day investment decisions for each applicable Series are made by that Series' Sub-Adviser, which has discretionary authority to invest the assets or a portion of the assets of that Series subject to the general supervision of the Adviser and the Board. The Adviser currently compensates each Sub-Adviser out of the advisory fees paid to the Adviser under the Investment Advisory Agreement; in the future, Sub-Advised Series may directly pay advisory fees to the Sub-Advisers.

7. Sub-Advised Series will inform shareholders of the hiring of a new Sub-Adviser pursuant to the following procedures (''Notice and Access Procedures''): (a) Within 90 days after a new Sub-Adviser is hired for any Sub-Advised Series, that Sub-Advised Series will send its shareholders either a Multi-Manager Notice or a Multi-Manager Notice and Multi-Manager Information Statement; [8] and (b) the Sub-Advised Series will make the Multi-Manager Information Statement available on the Web site identified in the Multi-Manager Notice no later than when the Multi-Manager Notice (or Multi-Manager Notice and Multi-Manager Information Statement) is first sent to shareholders, and will maintain it on that Web site for at least 90 days thereafter. In the circumstances described in the application, a proxy solicitation to approve the appointment of new Sub-Advisers provides no more meaningful information to shareholders than the proposed Multi-Manager Information Statement. Applicants state that each Board would comply with the requirements of sections 15(a) and 15(c) of the Act before entering into or amending a Sub-Advisory Agreement.

8. Applicants also request an order exempting the Sub-Advised Series from certain disclosure obligations that may require each Sub-Advised Series to disclose fees paid by the Adviser to each Sub-Adviser. Applicants seek relief to permit each Sub-Advised Series to disclose (as a dollar amount and a percentage of the Sub-Advised Series' net assets): (a) The aggregate fees paid to the Adviser and any Wholly-Owned Sub-Advisers; (b) the aggregate fees paid to Non-Affiliated Sub-Advisers; and (c) the fee paid to each Affiliated Sub-Adviser (collectively, the ''Aggregate Fee Disclosure'').

Applicants' Legal Analysis

1. Section 15(a) of the Act states, in part, that it is unlawful for any person to act as an investment adviser to a registered investment company ''except pursuant to a written contract, which contract, whether with such registered company or with an investment adviser of such registered company, has been approved by the vote of a majority of the outstanding voting securities of such registered company.'' Rule 18f–2 under the Act provides that each series or class of stock in a series investment company affected by a matter must approve that matter if the Act requires shareholder approval.

2. Form N–1A is the registration statement used by open-end investment companies. Item 19(a)(3) of Form N–1A requires a registered investment company to disclose in its statement of additional information the method of computing the ''advisory fee payable'' by the investment company, including the total dollar amounts that the investment company ''paid to the adviser (aggregated with amounts paid to affiliated advisers, if any), and any advisers who are not affiliated persons of the adviser, under the investment advisory contract for the last three fiscal years.''

3. Rule 20a–1 under the Act requires proxies solicited with respect to a registered investment company to comply with Schedule 14A under the Exchange Act. Items 22(c)(1)(ii), 22(c)(1)(iii), 22(c)(8) and 22(c)(9) of Schedule 14A, taken together, require a proxy statement for a shareholder meeting at which the advisory contract will be voted upon to include the ''rate of compensation of the investment adviser,'' the ''aggregate amount of the investment adviser's fee,'' a description of the ''terms of the contract to be acted upon,'' and, if a change in the advisory fee is proposed, the existing and proposed fees and the difference between the two fees.

4. Regulation S–X sets forth the requirements for financial statements required to be included as part of a registered investment company's registration statement and shareholder reports filed with the Commission. Sections 6–07(2)(a), (b), and (c) of Regulation S–X require a registered investment company to include in its financial statement information about the investment advisory fees.

5. Section 6(c) of the Act provides that the Commission by order upon application may conditionally or unconditionally exempt any person, security, or transaction or any class or classes of persons, securities, or transactions from any provisions of the Act, or from any rule thereunder, if such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants state that their requested relief meets this standard for the reasons discussed below.

6. Applicants assert that the shareholders expect the Adviser, subject to the review and approval of the Board, to select the Sub-Advisers that are suited to achieve the Series' investment objective. Applicants assert that, from the perspective of the shareholder, the role of the Sub-Adviser is substantially equivalent to the role of the individual portfolio managers employed by an investment adviser to a traditional investment company. Applicants believe that permitting the Adviser to perform the duties for which the shareholders of the Sub-Advised Series are paying the Adviser—the selection, supervision and evaluation of the Sub-Adviser—without incurring unnecessary delays or expenses is appropriate in the interest of the Series' shareholders and will allow the Series to operate more efficiently. Applicants state that the Investment Advisory Agreement will continue to be fully subject to section 15(a) of the Act and rule 18f–2 under the Act and approved by the Board, including a majority of the Independent Trustees, in the manner required by sections 15(a) and 15(c) of the Act. Applicants are not seeking an exemption with respect to the Investment Advisory Agreement.

7. Applicants assert that disclosure of the individual fees that the Adviser would pay to the Sub-Advisers of Sub-Advised Series that operate under the Manager of Managers Structure would not serve any meaningful purpose. Applicants contend that the primary

[8] A ''Multi-Manager Notice'' will be modeled on a Notice of Internet Availability as defined in rule 14a–16 under the Securities Exchange Act of 1934 (''Exchange Act''), and specifically will, among other things: (a) summarize the relevant information regarding the new Sub-Adviser; (b) inform shareholders that the Multi-Manager Information Statement is available on a Web site; (c) provide the Web site address; (d) state the time period during which the Multi-Manager Information Statement will remain available on that Web site; (e) provide instructions for accessing and printing the Multi-Manager Information Statement; and (f) instruct the shareholder that a paper or email copy of the Multi-Manager Information Statement may be obtained, without charge, by contacting the Sub-Advised Series.

A ''Multi-Manager Information Statement'' will meet the requirements of Regulation 14C, Schedule 14C and Item 22 of Schedule 14A under the Exchange Act for an information statement, except as modified by the order to permit Aggregate Fee Disclosure (as defined below). Multi-Manager Information Statements will be filed with the Commission via the EDGAR system.

reasons for requiring disclosure of individual fees paid to Sub-Advisers are to inform shareholders of expenses to be charged by a particular Sub-Advised Series and to enable shareholders to compare the fees to those of other comparable investment companies. Applicants believe that the requested relief satisfies these objectives because the advisory fee paid to the Adviser, or the Aggregate Fee Disclosure, in the case of a Sub-Advised Series that directly compensates a Sub-Adviser, will be fully disclosed and, therefore, shareholders will know what the Sub-Advised Series' fees and expenses are and will be able to compare the advisory fees a Sub-Advised Series is charged to those of other investment companies. Applicants assert that the requested disclosure relief would benefit shareholders of the Sub-Advised Series because it would improve the Adviser's ability to negotiate the fees paid to Sub-Advisers. Applicants state that the Adviser may be able to negotiate rates that are below a Sub-Adviser's ''posted'' amounts if the Adviser is not required to disclose the Sub-Advisers' fees to the public. Applicants submit that the relief requested to use Aggregate Fee Disclosure will encourage Sub-Advisers to negotiate lower sub-advisory fees with the Adviser if the lower fees are not required to be made public.

8. For the reasons discussed above, applicants submit that the requested relief meets the standards for relief under section 6(c) of the Act. Applicants state that the operation of the Sub-Advised Series in the manner described in the application must be approved by shareholders of a Sub-Advised Series before that Sub-Advised Series may rely on the requested relief. In addition, applicants state that the proposed conditions to the requested relief are designed to address any potential conflicts of interest, including any posed by the use of Wholly-Owned Sub-Advisers, and provide that shareholders are informed when new Sub-Advisers are hired. Applicants assert that conditions 6, 7, 9, 10 and 11 are designed to provide the Board with sufficient independence and the resources and information it needs to monitor and address any conflicts of interest with affiliated persons of the Adviser, including Wholly-Owned Sub-Advisers. Applicants state that, accordingly, they believe the requested relief is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

Applicants' Conditions

Applicants agree that any order granting the requested relief will be subject to the following conditions:

1. Before a Sub-Advised Series may rely on the order requested in the application, the operation of the Sub-Advised Series in the manner described in the application, including the hiring of Wholly-Owned Sub-Advisers, will be approved by a majority of the Sub-Advised Series' outstanding voting securities as defined in the Act, or, in the case of a Sub-Advised Series whose public shareholders purchase shares on the basis of a prospectus containing the disclosure contemplated by condition 2 below, by the sole initial shareholder before offering the Sub-Advised Series' shares to the public.

2. The prospectus for each Sub-Advised Series will disclose the existence, substance, and effect of any order granted pursuant to the application. Each Sub-Advised Series will hold itself out to the public as employing the Manager of Managers Structure. Each prospectus will prominently disclose that the Adviser has the ultimate responsibility, subject to oversight by the Board, to oversee the Sub-Advisers and recommend their hiring, termination and replacement.

3. The Adviser will provide general management services to each Sub-Advised Series, including overall supervisory responsibility for the general management and investment of the Sub-Advised Series' assets, and, subject to review and approval by the Board, the Adviser will: (a) Set the Sub-Advised Series' overall investment strategies; (b) evaluate, select, and recommend Sub-Advisers to manage all or a portion of the Sub-Advised Series' assets; and (c) implement procedures reasonably designed to ensure that the Sub-Advisers comply with a Sub-Advised Series' investment objectives, policies and restrictions. Subject to review by the Board, the Adviser will (a) when appropriate, allocate and reallocate the Sub-Advised Series' assets among multiple Sub-Advisers; and (b) monitor and evaluate the performance of Sub-Advisers.

4. A Sub-Advised Series will not make any Ineligible Sub-Adviser Changes without the approval of the shareholders of the applicable Sub-Advised Series.

5. A Sub-Advised Series will inform shareholders of the hiring of a new Sub-Adviser within 90 days after the hiring of the new Sub-Adviser pursuant to the Notice and Access Procedures.

6. At all times, at least a majority of the Board will be Independent Trustees, and the selection and nomination of new or additional Independent Trustees will be placed within the discretion of the then-existing Independent Trustees.

7. Independent Legal Counsel, as defined in rule 0–1(a)(6) under the Act, will be engaged to represent the Independent Trustees. The selection of such counsel will be within the discretion of the then-existing Independent Trustees.

8. The Adviser will provide the Board, no less frequently than quarterly, with information about the profitability of the Adviser on a per Sub-Advised Series basis. The information will reflect the impact on profitability of the hiring or termination of any Sub-Adviser during the applicable quarter.

9. Whenever a Sub-Adviser is hired or terminated, the Adviser will provide the Board with information showing the expected impact on the profitability of the Adviser.

10. Whenever a Sub-Adviser change is proposed for a Sub-Advised Series with an Affiliated Sub-Adviser or a Wholly-Owned Sub-Adviser, the Board, including a majority of the Independent Trustees, will make a separate finding, reflected in the Trust's Board minutes, that such change is in the best interests of the Sub-Advised Series and its shareholders and does not involve a conflict of interest from which the Adviser or the Affiliated Sub-Adviser or Wholly-Owned Sub-Adviser derives an inappropriate advantage.

11. No trustee or officer of the Trust or of a Sub-Advised Series or any partner, director, manager or officer of the Adviser will own directly or indirectly (other than through a pooled investment vehicle that is not controlled by such person) any interest in a Sub-Adviser except for: (a) Ownership of interests in the Adviser or any entity that controls, is controlled by, or is under common control with the Adviser; or (b) ownership of less than 1% of the outstanding securities of any class of equity or debt of a publicly traded company that is either a Sub-Adviser or an entity that controls, is controlled by, or is under common control with a Sub-Adviser.

12. Each Sub-Advised Series will disclose the Aggregate Fee Disclosure in its registration statement.

13. In the event the Commission adopts a rule under the Act providing substantially similar relief to that requested in the application, the requested order will expire on the effective date of that rule.

14. For Sub-Advised Series that pay fees to a Sub-Adviser directly from fund assets, any changes to a Sub-Advisory Agreement that would result in an

increase in the total management and advisory fees payable by a Sub-Advised Series will be required to be approved by the shareholders of the Sub-Advised Series.

For the Commission, by the Division of Investment Management, under delegated authority.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–07947 Filed 4–4–13; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–69275; File No. 4–660]

Fixed Income Roundtable

AGENCY: Securities and Exchange Commission.

ACTION: Notice of roundtable discussion; request for comment.

SUMMARY: The Securities and Exchange Commission will host a one day roundtable to discuss the current market structure and potential ways to improve the transparency, liquidity, efficiency, and other aspects of fixed income markets. The roundtable will focus on the municipal securities, corporate bonds, and asset-backed securities markets.

The roundtable discussion will be held in the multi-purpose room of the Securities and Exchange Commission headquarters at 100 F Street NE., in Washington, DC on April 16, 2013 beginning at 8:45 a.m. and ending at approximately 4:15 p.m. The public is invited to observe the roundtable discussion. Seating will be available on a first-come, first-served basis. The roundtable discussion also will be available via webcast on the Commission's Web site at *www.sec.gov.*

The roundtable will consist of four panels. The participants in the first panel will discuss the current market structure for municipal securities. The participants in the second panel will discuss the current market structure for corporate bonds and asset-backed securities. The participants in the third panel will discuss potential improvements to the market structure for municipal securities. The participants in the fourth panel will discuss potential improvements to the market structure for corporate bonds and asset-backed securities.

DATES: The roundtable discussion will take place on April 16, 2013. The Commission will accept comments regarding issues addressed at the roundtable until May 7, 2013.

ADDRESSES: Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/other.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number 4–660 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 4–660. This file number should be included on the subject line if email is used. To help us 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/other.shtml*). Comments are also available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. All comments received will be posted without change; we do not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

FOR FURTHER INFORMATION CONTACT: Ronesha A. Butler, Special Counsel, at (202) 551–5629, Division of Trading and Markets, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–7010.

Dated: April 2, 2013.

By the Commission.

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2013–07983 Filed 4–4–13; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 9398; Release No. 69265]

Securities Act of 1933; Securities Exchange Act of 1934; Order Regarding Review of FASB Accounting Support Fee for 2013 Under Section 109 of the Sarbanes-Oxley Act of 2002

April 2, 2013.

The Sarbanes-Oxley Act of 2002 (the ''Act'') provides that the Securities and Exchange Commission (the ''Commission'') may recognize, as generally accepted for purposes of the securities laws, any accounting principles established by a standard setting body that meets certain criteria. Consequently, Section 109 of the Act provides that all of the budget of such a standard setting body shall be payable from an annual accounting support fee assessed and collected against each issuer, as may be necessary or appropriate to pay for the budget and provide for the expenses of the standard setting body, and to provide for an independent, stable source of funding, subject to review by the Commission. Under Section 109(f) of the Act, the amount of fees collected for a fiscal year shall not exceed the ''recoverable budget expenses'' of the standard setting body. Section 109(h) amends Section 13(b)(2) of the Securities Exchange Act of 1934 to require issuers to pay the allocable share of a reasonable annual accounting support fee or fees, determined in accordance with Section 109 of the Act.

On April 25, 2003, the Commission issued a policy statement concluding that the Financial Accounting Standards Board (''FASB'') and its parent organization, the Financial Accounting Foundation (''FAF''), satisfied the criteria for an accounting standard-setting body under the Act, and recognizing the FASB's financial accounting and reporting standards as ''generally accepted'' under Section 108 of the Act.[1] As a consequence of that recognition, the Commission undertook a review of the FASB's accounting support fee for calendar year 2013. In connection with its review, the Commission also reviewed the budget for the FAF and the FASB for calendar year 2013.

Section 109 of the Act also provides that the standard setting body can have additional sources of revenue for its activities, such as earnings from sales of publications, provided that each additional source of revenue shall not jeopardize, in the judgment of the Commission, the actual or perceived independence of the standard setter. In this regard, the Commission also considered the interrelation of the operating budgets of the FAF, the FASB, and the Governmental Accounting Standards Board (''GASB''), the FASB's sister organization, which sets accounting standards used by state and local government entities. The Commission has been advised by the FAF that neither the FAF, the FASB, nor the GASB accept contributions from the accounting profession.

The Commission understands that the Office of Management and Budget

[1] Financial Reporting Release No. 70.

(''OMB'') has determined that the FASB is included in sequestration anticipated by the the Budget Control Act of 2011 (''BCA'').[2] So long as sequestration is applicable, we anticipate that the FAF will work with the Commission and Commission staff as appropriate regarding its implementation of sequestration. In that event, the Commission also requests the FAF to provide the Commission with information regarding the FAF's plans for implementation of sequestration, including how it will impact 2013 spending for each of the FAF's program areas and cost categories.

After its review, the Commission determined that the 2013 annual accounting support fee for the FASB is consistent with Section 109 of the Act. Accordingly,

It is ordered, pursuant to Section 109 of the Act, that the FASB may act in accordance with this determination of the Commission.

By the Commission.

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2013–07984 Filed 4–4–13; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–69259; File No. SR–BOX–2013–17]

Self-Regulatory Organizations; BOX Options Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 12140 (Imposition of Fines for Minor Rule Violations)

March 29, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that, on March 22, 2013, BOX Options Exchange LLC (the ''Exchange'' or ''BOX'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 12140 (Imposition of Fines for Minor Rule Violations) to correct certain cross references, clarify the calculation and review periods applicable to certain violations, and amend the sanction amounts for trade-through violations. The text of the proposed rule change is available from the principal office of the Exchange, at the Commission's Public Reference Room and also on the Exchange's Internet Web site at *http://boxexchange.com.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 12140 (Imposition of Fines for Minor Rule Violations) to correct certain cross references, clarify the calculation and review periods applicable to certain violations, and amend the sanction amounts for trade-through violations.

Exchange Rule 12140 provides that in lieu of commencing a disciplinary proceeding, the Exchange may, subject to the certain requirements set forth in the Rule, impose a fine, not to exceed $5,000, on any Options Participant, or person associated with or employed by an Options Participant, with respect to any Rule violation listed in Rule 12140(d). Any fine imposed pursuant to this Rule that (i) does not exceed $2,500 and (ii) is not contested, shall be reported on a periodic basis, except as may otherwise be required by Rule 19d–1 under the Act or by any other regulatory authority. Further, the Rule provides that any person against whom a fine is imposed under the Rule shall be served with a written statement setting forth (i) the Rule(s) allegedly violated; (ii) the act or omission constituting each such violation; (iii) the fine imposed for each violation; and (iv) the date by which such determination becomes final and such fine must be paid or contested as provided below, which date shall be not less than thirty (30) calendar days after the date of service of such written statement.

First, the Exchange proposes to amend Rule 12140(b) to change the date that a determination becomes final and the fine must be paid or contested from thirty to twenty-five (25) calendar days after the date of service of the written notice of an alleged violation. This change is meant to bring the final determination time period in line with the time period to file an answer under Rule 12050. With this change a Participant will have twenty-five (25) days to file an answer, after which the determination will become final and the fine must be paid or contested.

Next, the Exchange proposes to amend Rule 12140(d)(1) to clarify that violations of the Positions Limit Rule will be progressive for the number of cumulative violations within any rolling 24-month period.

The Exchange also proposes to amend Rule 12140(d)(2) to clarify the time period that may be subject to penalty for late focus reports will be 1–30 calendar days, 31 to 60 days, 61–90 days and over 90 days.

The Exchange proposes to amend Rule 12140(d)(5), (6), (11), and (12) to add and correct citations to Rule 8040(a)(7), 8050(e), 8030(e), and 8050(c)(2)–(4) regarding Market Maker obligations. Additionally proposed amendments to Rule 12140(d)(6) clarify the review period for calculating violations of a Market Maker's quoting obligations, and specify additional sanctions that may apply to Market Maker violations of their quoting obligations for consecutive business days within the review period.

The Exchange proposes to add to Rule 12140(d)(8) specific references to Rules 2020, 2040, and 2050 regarding a firm's obligation to timely file amendments to Form U–4, Form U–5, and Form BD. Additionally, the Exchange proposes to specify that a fourth violation, or any violation thereafter, may result in formal disciplinary action against a firm.

The Exchange proposes to add to Rule 12140(d)(9) specific references to the rule provisions related to Contrary Exercise Advice (Rule 9000(c)–(e), 9000(g), and 9000(h)).

The Exchange proposes to amend Rule 12140(d)(10) to add and correct citations to Rule 15020 regarding Locked and Crossed Market Violations.

Finally, the Exchange proposes to amend Rule 12140(d)(13) regarding Trade-Through Violations. The

[2] See ''OMB Report Pursuant to the Sequestration Transparency Act of 2012'' (P.L. 112–155), page 222 of 224 at: *http://www.whitehouse.gov/sites/default/files/omb/assets/legislative_reports/stareport.pdf.*

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

Exchange proposes to add and correct citations to Rule 15010 regarding trade-throughs, and to clarify that for purposes of calculating the number of violations during a period subject to sanctions, a violation shall occur when an Options Participant engages in a pattern or practice of trading through better prices available on other exchanges. In addition, the Exchange proposes to extend the period of time used in calculating the number of trade-through violations from a twelve-month rolling period to a twenty-four month rolling period, and increase the sanction amounts that an Options Participant will be subject to under this rule. An initial trade-through violation will now have a sanction of $500, the second violation will have a sanction of $1,000, the third violation will have a sanction of $2,500, and any subsequent violations will be have a sanction of $5,000 or Formal Disciplinary Action. These changes are based on the rules of the Chicago Board Option Exchange, Inc. (''CBOE'').[3].

2. Statutory Basis

The Exchange believes that the proposal is consistent with the requirements of Section 6(b) of the Securities Exchange Act of 1934 (the ''Act''),[4] in general, and Section 6(b)(5) of the Act,[5] in particular, in that it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism for a free and open market and a national market system and, in general, to protect investors and the public interest. In particular, the Exchange believes the proposed change is consistent with Section 6(b) of the Act, which further requires that the Exchange enforce compliance with, and provide appropriate discipline for violations of, Commission and Exchange rules. Finally, the Exchange believes that the proposal is consistent with the public interest, the protection of investors, or otherwise in furtherance of the purposes of the Act, because Rule 12140 strengthens the Exchange's ability to carry out its oversight and enforcement responsibilities as an SRO in cases where full disciplinary proceedings may be unsuitable in view of the minor nature of the particular violation.

[3] *See* CBOE Rule 17.50(g)(12).

[4] 15 U.S.C. 78f(b).

[5] 15 U.S.C. 78f(b)(5).

B. Self-Regulatory Organization's Statement on Burden on Competition

Because the proposed rule change does not impose any new or additional burden on BOX Options Participants, and only corrects and clarifies certain information in Rule 12140 with regard to the Exchange Minor Rule Violation Plan, 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

The Exchange has neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

This proposed rule change is filed for immediate effectiveness pursuant to paragraph (A) of section 19(b)(3) of the Exchange Act [6] and Rule 19b-4(f)(6) thereunder.[7] The Exchange asserts that this proposed rule change does not (i) significantly affect the protection of investors or the public interest, (ii) impose any significant burden on competition, and, (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest.

Because the proposed rule change does not impose any new or additional burden on BOX Options Participants, and only corrects and clarifies certain information in Rule 12140 with regard to the Exchange Minor Rule Violation Plan, the Exchange believes this rule filing qualifies as a ''non-controversial'' rule change under Rule 19b–4(f)(6) of the Act and requests that the Commission make the proposed change effective and operative upon filing. [8]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend the rule change if it appears to the Commission that the action is necessary or appropriate in the public interest, for the protection of investors, or would otherwise further 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.

[6] 15 U.S.C. 78s(b)(3)(A).

[7] 17 CFR 240.19b–4(f)(6).

[8] As required under Rule 19b–4(f)(6)(iii), the Exchange provided the Commission with written notice of its intent to file the proposed rule change along with a brief description and the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BOX–2013–17 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–BOX–2013–17.* This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of 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–BOX–

2013–17 and should be submitted on or before April 26, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[9]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–07940 Filed 4–4–13; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–69262; File No. SR–FINRA–2013–019]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to FINRA Rule 0180 (Application of Rules to Security-Based Swaps)

April 1, 2013.

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 March 18, 2013, Financial Industry Regulatory Authority, Inc. (''FINRA'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by FINRA. FINRA has designated the proposed rule change as constituting a ''non-controversial'' rule change under paragraph (f)(6) of Rule 19b–4 under the Act,[3] which renders the proposal effective upon receipt of this filing by the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

FINRA is proposing to extend the expiration date of FINRA Rule 0180 (Application of Rules to Security-Based Swaps) to February 11, 2014. FINRA Rule 0180 temporarily limits, with certain exceptions, the application of FINRA rules with respect to security-based swaps.

The text of the proposed rule change is available on FINRA's Web site at *http://www.finra.org,* at the principal office of FINRA and at the Commission's Public Reference Room.

[9] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 17 CFR 240.19b–4(f)(6).

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FINRA included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. FINRA has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

On July 1, 2011, the SEC issued an Order granting temporary exemptive relief (the ''Temporary Exemptions'') from compliance with certain provisions of the Exchange Act in connection with the revision, pursuant to Title VII of the Dodd-Frank Wall Street Reform and Consumer Protection Act (the ''Dodd-Frank Act''),[4] of the Exchange Act definition of ''security'' to encompass security-based swaps.[5] In tandem with the Commission's action, on July 8, 2011, FINRA filed for immediate effectiveness FINRA Rule 0180,[6] which, with certain exceptions, is intended to temporarily limit the application of FINRA rules[7] with respect to security-based swaps, thereby helping to avoid undue market disruptions resulting from the change to the definition of ''security'' under the Act.[8]

The Commission, noting the need to avoid a potential unnecessary disruption to the security-based swap market in the absence of an extension of the Temporary Exemptions, and the need for additional time to consider the potential impact of the revision of the Exchange Act definition of ''security'' in light of recent Commission rulemaking efforts under Title VII of the Dodd-Frank Act, has issued an Order extending the expiration date of the Temporary Exemptions until February 11, 2014.[9] The Commission noted that extending the Temporary Exemptions would facilitate a coordinated consideration of these issues with the relief provided pursuant to FINRA Rule 0180. FINRA, in establishing FINRA Rule 0180, noted its intent to align the rule's expiration date with the expiration of the Temporary Exemptions.[10] FINRA believes it is appropriate and in the public interest, in light of the

[4] Public Law 111–203, 124 Stat. 1376 (2010).

[5] *See* Securities Exchange Act Release No. 64795 (July 1, 2011), 76 FR 39927 (July 7, 2011) (Order Granting Temporary Exemptions Under the Securities Exchange Act of 1934 in Connection With the Pending Revision of the Definition of ''Security'' To Encompass Security-Based Swaps, and Request for Comment) (the ''Exemptive Release''). The term ''security-based swap'' is defined in Section 761 of the Dodd-Frank Act. *See also* Securities Exchange Act Release No. 67453 (July 18, 2012), 77 FR 48208 (August 13, 2012) (Further Definition of ''Swap,'' ''Security-Based Swap,'' and ''Security-Based Swap Agreement''; Mixed Swaps; Security-Based Swap Agreement Recordkeeping).

[6] *See* Securities Exchange Act Release No. 64884 (July 14, 2011), 76 FR 42755 (July 19, 2011) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change; File No. SR–FINRA–2011–033) (''FINRA Rule 0180 Notice of Filing''). *See also* Securities Exchange Act Release No. 66156 (January 13, 2012), 77 FR 3027 (January 20, 2012) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change; File No. SR–FINRA–2012–004) (extending the expiration date of FINRA Rule 0180 to January 17, 2013); Securities Exchange Act Release No. 68471 (December 19, 2012), 77 FR 76113 (December 26, 2012) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change; File No. SR–FINRA–2012–056) (extending the expiration date of FINRA Rule 0180 to July 17, 2013).

[7] The current FINRA rulebook consists of: (1) FINRA Rules; (2) NASD Rules; and (3) rules incorporated from NYSE (''Incorporated NYSE Rules''). 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. 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).

[8] In its Exemptive Release, the Commission noted that the relief is targeted and does not include, for instance, relief from the Act's antifraud and anti-manipulation provisions. FINRA has noted that FINRA Rule 0180 is similarly targeted. For instance, paragraph (a) of FINRA Rule 0180 provides that FINRA rules shall not apply to members' activities and positions with respect to security-based swaps, except for FINRA Rules 2010 (Standards of Commercial Honor and Principles of Trade), 2020 (Use of Manipulative, Deceptive or Other Fraudulent Devices), 3310 (Anti-Money Laundering Compliance Program) and 4240 (Margin Requirements for Credit Default Swaps). *See also* paragraphs (b) and (c) of FINRA Rule 0180 (addressing the applicability of additional rules) and FINRA Rule 0180 Notice of Filing.

[9] *See* Securities Exchange Act Release No. 68864 (February 7, 2013), 78 FR 10218 (February 13, 2013) (Order Extending Temporary Exemptions Under the Securities Exchange Act of 1934 in Connection With the Revision of the Definition of ''Security'' to Encompass Security-Based Swaps, and Request for Comment) (''Temporary Exemptions Extension Release''). *See also* Securities Exchange Act Release No. 68753 (January 29, 2013), 78 FR 7654 (February 4, 2013) (Extension of Exemptions for Security-Based Swaps) (extending the expiration dates in interim final rules that provide exemptions under the Securities Act of 1933 (the ''Securities Act''), the Exchange Act, and the Trust Indenture Act of 1939 for those security-based swaps that prior to July 16, 2011 were security-based swap agreements and are defined as ''securities'' under the Securities Act and the Exchange Act as of July 16, 2011 due solely to the provisions of Title VII of the Dodd-Frank Act).

[10] *See* FINRA Rule 0180 Notice of Filing.

Commission's action in the Temporary Exemptions Extension Release, to extend FINRA Rule 0180 for a limited period, to February 11, 2014, so as to coincide with the Commission's extension of the Temporary Exemptions.

FINRA has filed the proposed rule change for immediate effectiveness. FINRA is proposing that the implementation date of the proposed rule change will be July 17, 2013.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,[11] which requires, among other things, that FINRA rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest. FINRA believes that the proposed rule change would further the purposes of the Act because, consistent with the goals set forth by the Commission in the Exemptive Release and in the Temporary Exemptions Extension Release, the proposed rule change will help to avoid undue market disruption that could result if the expiration of FINRA Rule 0180 does not align with the expiration of the Temporary Exemptions.

B. Self-Regulatory Organization's Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. FINRA believes that the proposed rule change would prevent undue market disruption that would otherwise result if security-based swaps were, by virtue of the expansion of the Act's definition of ''security'' to encompass security-based swaps, subject to the application of all FINRA rules before the expiration of the Temporary Exemptions. FINRA believes that, by extending the expiration of FINRA Rule 0180, the proposed rule change will serve to promote regulatory clarity and consistency, thereby reducing burdens on the marketplace and facilitating investor protection.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

[11] 15 U.S.C. 78*o*–3(b)(6).

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [12] and Rule 19b–4(f)(6) thereunder.[13]

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 email to *rule-comments@sec.gov.* Please include File Number SR–FINRA–2013–019 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–FINRA–2013–019. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of FINRA. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions.

You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–FINRA–2013–019 and should be submitted on or before April 26, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–07941 Filed 4–4–13; 8:45 am]

BILLING CODE 8011–01–P

[12] 15 U.S.C. 78s(b)(3)(A).

[13] 17 CFR 240.19b–4(f)(6).

[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–69253; File No. SR-Phlx–2013–23]

Self-Regulatory Organizations; NASDAQ OMX PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Routing Fees and the Customer Rebate Program

March 28, 2013.

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 March 19, 2013, 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.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Section V of the Pricing Schedule entitled ''Routing Fees.'' The Exchange is also proposing to amend the Customer Rebate Program.

While changes to the Pricing Schedule pursuant to this proposal are effective upon filing, the Exchange has designated the proposed amendment to be operative on April 1, 2013.

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaqomxphlx.cchwallstreet.com/,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this filing is to amend Routing Fees in Section V of the Pricing Schedule in order to recoup costs that the Exchange incurs for routing and executing orders in equity options to various away markets. The Exchange is also proposing to amend the Customer Rebate Program to continue to incentivize participants to transact Customer orders.

Routing

Today, the Exchange calculates Routing Fees by assessing certain Exchange costs related to routing orders to away markets plus the away market's transaction fee. The Exchange assesses a $0.05 per contract [3] fixed Routing Fee when routing orders to the NASDAQ Options Market LLC (''NOM'') and NASDAQ OMX BX, Inc. (''BX Options'') and a $0.11 per contract [4] fixed Routing Fee to all other options exchanges in addition to the actual transaction fee or rebate paid by the away market. The fixed Routing Fee is based on costs that are incurred by the Exchange when routing to an away market in addition to the away market's transaction fee. For example, the Exchange incurs a fee when it utilizes Nasdaq Options Services LLC (''NOS''), a member of the Exchange and the Exchange's exclusive order router,[5] to route orders in options listed and open for trading on the PHLX XL system to destination markets. Each time NOS routes to away markets NOS incurs a clearing-related cost [6] and, in the case of certain exchanges, a transaction fee is also charged in certain symbols, which fees are passed through to the Exchange. The Exchange also incurs administrative and technical costs associated with operating NOS, membership fees at away markets, Options Regulatory Fees (''ORFs'') and technical costs associated with routing options. The transaction fee assessed by the Exchange is based on the away market's actual transaction fee or rebate for a particular market participant at the time that the order was entered into the Exchange's trading system. This transaction fee is calculated on an order-by-order basis, since different away markets charge different amounts. In the event that there is no transaction fee or rebate assessed by the away market, the only fee assessed is the fixed Routing Fee. With respect to the rebate, the Exchange pays a market participant the rebate offered by an away market where there is such a rebate. Any rebate available is netted against a fee assessed by the Exchange.[7]

C2 recently filed a rule change to amend its transaction fees and rebates for simple, non-complex orders, in equity options classes which became operative on February 1, 2013.[8] As a result of that filing the Exchange amended its Pricing Schedule and today assesses non-Customer simple, non-complex orders in equity options (single stock) that are routed to C2 a Routing Fee which includes a fixed cost of $0.11 per contract plus a flat rate of $0.85 per contract, except with respect to Customers.[9] With respect to Customers, the Exchange does not pass the rebate offered by C2, rather, Customer simple, non-complex orders in equity options (single stock) that are routed to C2 are assessed $0.00 per contract.

The Exchange is proposing to further simplify its Routing Fees by assessing a flat rate of $0.95 per contract on all non-Customer orders routed to any away market. The Exchange would no longer pass any rebate paid by an away market for non-Customer orders. With respect to Customer orders, the Exchange is proposing to continue to assess Customer orders routed to NOM a fixed fee of $0.05 per contract (''Fixed Fee'') in addition to the actual transaction fee assessed by the away market. This fee is not changing. With respect to Customer orders that are routed to BX Options, the Exchange will not assess a Routing Fee and will not pass the rebate. Today, BX Options pays a Customer Rebate to Remove Liquidity as follows: Customers are paid $0.12 per contract in IWM, SPY and QQQ, $0.32 per contract in All Other Penny Pilot Options and $0.70 per contract in Non-Penny Pilot Options.[10] The Exchange is proposing to not assess a Routing Fee when routing orders to BX Options because that exchange pays a rebate. Instead of netting the customer rebate paid by BX

[3] In a previous rule filing, the Exchange discussed the manner in which it analyzed costs related to routing to PHLX and NOM and determined the costs are lower as compared to other away markets because NOS is utilized by all three exchanges to route orders. In that filing the Exchange noted that because Phlx, BX Options and NOM all utilize NOS, the cost to the Exchange is less as compared to routing to other away markets. In addition the fixed costs are reduced because NOS is owned and operated by NASDAQ OMX and the three exchanges and NOS share common technology and related operational functions. *See* Securities Exchange Act Release No. 68213 (November 13, 2012), 77 FR 69530 (November 19, 2012) (SR–Phlx–2012–129).

[4] The $0.11 per contract Fixed Fee would apply to all options exchanges other than BX Options and NOM, which are discussed separately in this proposal. The Exchange anticipates that if other options exchanges are approved by the Commission after the filing of this proposal, those exchanges would be assessed the $0.11 per contract fee applicable to ''all other options exchanges.''

[5] In May 2009, the Exchange adopted Rule 1080(m)(iii)(A) to establish Nasdaq Options Services LLC (''NOS''), a member of the Exchange, as the Exchange's exclusive order router. *See* Securities Exchange Act Release No. 59995 (May 28, 2009), 74 FR 26750 (June 3, 2009) (SR–Phlx–2009–32). NOS is utilized by the Exchange's fully automated options trading system, PHLX XL.® ''PHLX XL'' is the Exchange's automated options trading system.

[6] The Options Clearing Corporation (''OCC'') assesses a clearing fee of $0.01 per contract side. *See* Securities Exchange Act Release No. 68025 (October 10, 2012), 77 FR 63398 (October 16, 2012) (SR–OCC–2012–18).

[7] For example, if a Customer order is routed to BOX, and BOX offers a customer rebate of $0.20 per contract, the Exchange would assess a $0.11 per contract fixed fee which would net against the rebate ($0.20 per contract in this example). The market participant for whom the Customer contract was routed would receive a $0.09 per contract rebate.

[8] *See* Securities Exchange Act Release No. 68792 (January 31, 2013), 78 FR 8621 (February 6, 2013) (SR–C2–2013–004).

[9] *See* Securities Exchange Act Release No. 68984 (February 25, 2013), 78 FR 13925 (March 1, 2013) (SR–Phlx–2013–17).

[10] *See* BX Options Rules at Chapter XV, Section 2(1).

Options against the fixed fee,[11] the Exchange would simply not assess a fee. Although market participants routing to BX Options will not receive a credit, as is the case today, market participants will not pay a Customer Routing Fee when their orders are routed to BX Options with this proposal. The Exchange proposes to assess a Customer Routing Fee of $0.11 per contract (''Fixed Fee'') in addition to the actual transaction fee when routing to an options exchange other than NOM and BX Options, as is the case today. The Exchange is amending the payment of rebates and will no longer pay rebates when routing Customer orders to an away market, instead the Exchange will not assess a Routing Fee if a Customer order is routed to an away market that pays a rebate.

Customer Rebate Program

The Exchange is proposing to relocate text from Section A of the Pricing Schedule to Section V (Routing) regarding credits applied to Routing Fees when a member organization qualifies for certain Customer rebate tiers. Today, a member organization qualifying for a Tier 2, 3 or 4 rebate in the Customer Rebate Program in Section A of the Pricing Schedule is entitled to receive a credit of $0.10 per contract toward the Routing Fee specified in Section V of the Pricing Schedule if a Customer order is routed to NOM and a $0.05 per contract credit if a Customer order is routed to BX Options. A member organization qualifying for a Tier 2, 3 or 4 rebate receives a credit of $0.16 per contract toward the Routing Fee specified in Section V of the Pricing Schedule if the Customer order is routed to an away market other than BX Options or NOM unless the away market transaction fee is $0.00 or the away market pays a rebate, in which case the member organization is entitled to receive a credit of $0.11 per contract toward the Routing Fee specified in Section V of the Pricing Schedule.

The Exchange is proposing to relocate this text to Section V of the Pricing Schedule because it relates to Routing Fees. The Exchange is also proposing to amend the text to provide that a member organization qualifying for a Tier 2, 3 or 4 rebate in the Customer Rebate Program in Section A of the Pricing Schedule is entitled to receive a credit equal to the Fixed Fee (either $0.05 or $0.11 per credit) plus $0.05 per contract, unless the away market transaction fee is $0.00 per contract or the away market pays a rebate, in which case the member organization is entitled to receive a credit equal to the Fixed Fee.

Finally, the Exchange is proposing to amend the Customer Rebate Program. Today, the Exchange's four tier Customer Rebate Program pays rebates based on the percentage thresholds of national customer multiply-listed options volume by month based on four Categories, A, B, C and D, of transactions. Specifically, a market participant's qualification for a rebate is based on the percentage of total national customer volume in Multiply Listed Options which are transacted monthly on Phlx. The percentage is the total number of electronically-delivered and executed Customer contracts in Multiply Listed Options, which includes equity, ETF and index options volume (excluding volume associated with electronic QCC Orders, as defined in Exchange Rule 1080(o), transacted on Phlx (''Qualifying Volume'') divided by Multiply Listed customer options volume, which also includes equity, ETF and Index options volume, as reported by The Options Clearing Corporation (''OCC''). The Exchange proposes to amend this qualification so that the Exchange would instead divide Qualifying Volume by total Multiply Listed equity and ETF options volume, as reported by OCC. By amending the calculation, the Exchange would exclude index volume that is included today from the total industry volume that qualifies member organizations for a rebate, which would mathematically result in advantaging member organizations by providing them the opportunity to achieve higher percentages because the indexes are excluded from the industry volume.

2. Statutory Basis

The Exchange believes that its proposal to amend its Pricing Schedule is consistent with Section 6(b) of the Act[12] in general, and furthers the objectives of Section 6(b)(4) of the Act,[13] in particular, in that it is an equitable allocation of reasonable fees and other charges among Exchange members.

Routing

The Exchange believes that its proposal to amend its non-Customer Routing Fees from a fixed fee plus actual transaction charges to a flat rate is reasonable because the flat rate makes it easier for market participants to anticipate the Routing Fees which they would be assessed at any given time. The Exchange believes that assessing all non-Customer orders the same flat rate will provide market participants with certainty with respect to Routing Fees. While, each destination market's transaction charge varies and there is a cost incurred by the Exchange when routing orders to away markets, including clearing costs, administrative and technical costs associated with operating NOS, membership fees at away markets, ORFs and technical costs associated with routing options, the Exchange believes that the proposed Routing Fees will enable it to recover the costs it incurs to route non-Customer orders to away markets. Other exchanges similarly assess a fixed rate fee to route non-Customer orders.[14]

The Exchange believes that its proposal to amend the non-Customer Routing Fees from a fixed fee plus actual transaction charges to a flat rate is equitable and not unfairly discriminatory because the Exchange would uniformly assess the same Routing Fees to all non-Customer market participants. Under its flat fee structure, taking all costs to the Exchange into account, the Exchange may operate at a slight gain or a slight loss for non-Customer orders routed to and executed at away markets. The proposed Routing Fee for non-Customer orders is an approximation of the maximum fees the Exchange will be charged for such executions, including costs, at away markets. As a general matter, the Exchange believes that the proposed fees will allow it to recoup and cover its costs of providing routing services for non-Customer orders. The Exchange believes that the fixed rate non-Customer Routing Fee is equitable and not unfairly discriminatory because market participants have the ability to directly route orders to an away market and avoid the Routing Fee. Also, market participants may submit orders to the Exchange as ineligible for routing or ''DNR'' to avoid Routing Fees.[15] It is important to note that when orders are routed to an away market they are routed based on price first.[16]

[11] BX Options does not assess a Customer a Fee to Remove Liquidity in any symbols today. *See* Chapter V, Section 2(1) of the BX Options Rules.

[12] 15 U.S.C. 78f(b).

[13] 15 U.S.C. 78f(b)(4).

[14] BATS Exchange, Inc. (''BATS'') assesses non-Customer fixed rates of $0.57 and $0.95 per contract when routing to away markets. *See* BATS BZX Exchange Fee Schedule. The Chicago Board Options Exchange Incorporated (''CBOE'') assesses non-Customer orders a $0.50 per contract routing fee in addition to the customary CBOE execution charges. *See* CBOE's Fees Schedule.

[15] *See* Rule 1066(h) (Certain Types of Orders Defined) and 1080(b)(i)(A) (PHLX XL and PHLX XL II).

[16] PHLX XL will route orders to away markets where the Exchange's disseminated bid or offer is inferior to the national best bid (best offer) (''NBBO'') price. *See* Rule 1080(m). The Phlx XL II system will contemporaneously route an order marked as an Intermarket Sweep Order (''ISO'') to

Continued

The Exchange believes that its proposal to not pass a rebate that is offered by an away market for non-Customers orders is reasonable because to the extent that another market is paying a rebate, the Exchange will assess a $0.95 per contract fee as its total cost in each instance. The Routing Fee is transparent and simple. If a market participant desires the rebate, the market participant has the option to direct the order to that away market. Other options exchanges today do not pass the rebate.[17] The Exchange believes that its proposal to not pass a rebate that is offered by an away market for non-Customers orders is equitable and not unfairly discriminatory because the Exchange would not pay such a rebate on any non-Customer order.

The Exchange believes that amending the Customer Routing Fee to BX Options from $0.05 per contract in addition to the actual transaction fee to $0.00 is reasonable, because, unlike NOM,[18] BX Options pays a Customer Rebate to Remove Liquidity as follows: Customers are paid $0.12 per contract in IWM, SPY and QQQ, $0.32 per contract in All Other Penny Pilot Options and $0.70 per contract in Non-Penny Pilot Options.[19] The Exchange believes that not assessing a fee for routing orders to BX Options, instead of netting the customer rebate paid by BX Options against the Fixed Fee [20] is reasonable because although market participants routing orders to BX Options will not receive a credit, as is the case today with respect to Customer orders routed to BX Options, the Routing Fee will be more transparent. Market participants will not pay a Customer Routing Fee when routing orders to BX Options with this proposal instead of the $0.05 per contract fee netted against the rebate, as is the case today. The Exchange believes that the proposed Customer Routing Fee to BX Options is equitable and not unfairly discriminatory because the proposal would apply uniformly to all market participants.

Further, the Exchange believes that it is reasonable to also not assess a Customer Routing Fee when routing to all other options exchanges, except NOM and BX Options, if the away market pays a rebate. The Exchange will continue to assess a Fixed Fee of $0.11 per contract plus the actual transaction charge assessed by the away market when routing to all other options exchanges, except NOM and BX Options, but instead of paying the rebate, as is the case today, the Exchange will not assess a Customer Routing Fee to that away market because the Exchange will collect the rebate to offset the fee. The Exchange believes that market participants will have more certainty as to the Customer Routing Fee that will be assessed by the Exchange. The Exchange believes that the proposed pricing for the Customer Routing Fee to all other away markets, except NOM and BX Options, is equitable and not unfairly discriminatory because while the Exchange may operate at a slight gain or a slight loss when routing Customer orders to the away market, depending on the rebate paid by the away market, the proposal would apply uniformly to all market participants when routing to an away market that pays a rebate.

The Exchange believes that it is reasonable, equitable and not unfairly discriminatory to continue to assess Customer orders that are routed to NOM a Fixed Fee of $0.05 per contract and orders that are routed to other away markets, other than NOM and BX Options, a Fixed Fee of $0.11 per contract because the cost, in terms of actual cash outlays, to the Exchange to route to NOM (and BX Options) [21] is lower. For example, costs related to routing to NOM are lower as compared to other away markets because NOS is utilized by all three exchanges to route orders.[22] NOS and the three NASDAQ OMX options markets have a common data center and staff that are responsible for the day-to-day operations of NOS. Because the three exchanges are in a common data center, Routing Fees are reduced because costly expenses related to, for example, telecommunication lines to obtain connectivity are avoided when routing orders in this instance. The costs related to connectivity to route orders to other NASDAQ OMX exchanges are de minimis. When routing orders to non-NASDAQ OMX exchanges, the Exchange incurs costly connectivity charges related to telecommunication lines and other related costs when routing orders. The Exchange believes it is reasonable, equitable and not unfairly discriminatory to pass along savings realized by leveraging NASDAQ OMX's infrastructure and scale to market participants when those orders are routed to NOM.

Finally, the Exchange believes that it is reasonable, equitable and not unfairly discriminatory to assess different fees for Customers orders as compared to non-Customer orders because the Exchange has traditionally assessed lower fees to Customers as compared to non-Customers. Customers will continue to receive the lowest fees or no fees when routing orders, as is the case today. Other options exchanges also assess lower Routing Fees for customer orders as compared to non-customer orders.[23]

Customer Rebates

The Exchange's proposal to amend the text, which was relocated from Section A of the Pricing Schedule to Section V, is reasonable because the Exchange will continue to credit market participants that qualify for Tiers 2, 3, and 4 in the Customer Rebate Program with the amendment in order to incentivize those market participants to transact Customer orders to the benefit of all market participants. The Exchange is proposing to relocate this text to Section V of the Pricing Schedule because it relates to Routing Fees.

The Exchange believes that the amendment to the relocated text is equitable and not unfairly discriminatory because the Exchange will continue to offer market participants that qualify for the credit a $0.10 credit for orders routed to NOM and a $0.05 credit for orders routed to BX Options, as is the case today. Also, orders routed to other away markets, with the exception of NOM and BX Options, will continue to receive a credit of $0.16 per contract (the $0.11 per contract Fixed Fee plus $0.05 per contract) toward the Routing Fee unless the away market transaction fee is $0.00 or the away market pays a rebate, the Exchange would pay a credit toward the

each away market disseminating prices better than the Exchange's price, for the lesser of: (a) The disseminated size of such away markets, or (b) the order size and, if order size remains after such routing, trade at the Exchange's disseminated bid or offer up to its disseminated size. If contracts still remain unexecuted after routing, they are posted on the book. Once on the book, should the order subsequently be locked or crossed by another market center, the Phlx XL II system will not route the order to the locking or crossing market center, with some exceptions noted in Rule 1080(m).

[17] *See* CBOE's Fees Schedule and International Securities Exchange LLC's (''ISE'') Fee Schedule.

[18] The NOM Customer Routing Fee is not being amended by this proposal. The Exchange would continue to assess Customer orders routed to NOM a $0.05 per contact Fixed Fee along plus the actual transaction fee.

[19] *See* BX Options Rules at Chapter XV, Section 2(1).

[20] BX Options does not assess a Customer a Fee to Remove Liquidity in any symbols today. *See* Chapter V, Section 2(1) of the BX Options Rules.

[21] With this proposal, the Exchange would not assess the $0.05 per contract Fixed Fee for routing orders to BX Options because that exchange pays Customer rebates, which the Exchange would retain to offset its cost.

[22] *See* Chapter VI, Section 11 of the NASDAQ and BX Options Rules and Phlx Rule 1080(m)(iii)(A).

[23] BATS assesses lower customer routing fees as compared to non-customer routing fees per the away market. For example BATS assesses ISE customer routing fees of $0.30 per contract and an ISE non-customer routing fee of $0.57 per contract. *See* BATS BZX Exchange Fee Schedule.

Routing Fee equal to the Fixed Fee of $0.11 per contract, as is the case today. The Exchange is proposing to amend the text to provide that a member organization qualifying for a Tier 2, 3 or 4 rebate in the Customer Rebate Program in Section A of the Pricing Schedule is entitled to receive a credit equal to the Fixed Fee (either $0.05 or $0.011 per credit) plus $0.05 per contract, unless the away market transaction fee is $0.00 per contract or the away market pays a rebate, in which case the member organization is entitled to receive a credit equal to the Fixed Fee. Although the Exchange is describing the credit differently in the rule text, the credit remains the same and the Exchange will continue to apply the credit in a uniform manner

Finally, the Exchange proposes to amend the Customer Rebate qualification to exclude indexes from the industry volume that is utilized to calculate a member organization's qualification for the Customer Rebate Tier. The Exchange believes that this amendment is reasonable because by including equity, ETF and index option volume in the calculation of member contracts and excluding indexes from the industry volume will provide member organizations an opportunity to achieve higher rebates because the industry volume number will be smaller.

The Exchange believes that its proposal to amend the Customer Rebate qualification is equitable and not unfairly discriminatory because the Customer Rebate Tiers would continue to apply in a uniform manner to all market participants.

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. The Exchange does not believe that the proposal creates intra-market competition because the Exchange is applying the same Routing Fees and credits to all market participants in the same manner dependent on the routing venue, with the exception of Customers. The Exchange has proposed separate Customer Routing Fees. Customers will continue to receive the lowest fees or no fees when routing orders, as is the case today. Other options exchanges also assess lower Routing Fees for customer orders as compared to non-customer orders.[24]

The Exchange's proposal would allow the Exchange to recoup its costs when routing orders to away markets when such orders are designated as available for routing by the market participant. The Exchange is passing along savings realized by leveraging NASDAQ OMX's infrastructure and scale to market participants when those orders are routed to NOM and is providing those saving to all market participants. Members and member organizations may choose to mark the order as ineligible for routing to avoid incurring these fees.[25] Today, other options exchanges also assess fixed routing fees to recoup costs incurred by the Exchange to route orders to away markets.[26]

Further, the amendments to the Customer Rebate Program are likewise applied in the same manner to all participants. The Exchange's proposal, which merely amends the manner in the Customer Rebate Tiers will be calculated, continues to impact all market participants equally. The Exchange does not believe that this proposal will impose a burden on competition.

The Exchange operates in a highly competitive market, comprised of eleven exchanges, in which market participants can easily and readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive. Accordingly, the fees that are assessed by the Exchange must remain competitive with fees charged by other venues and therefore must continue to be reasonable and equitably allocated to those members organizations that opt to direct orders to the Exchange rather than competing venues.

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.[27] 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 email to *rule-comments@sec.gov.* Please include File Number SR–Phlx–2013–23 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–2013–23. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions

[24] *Id.*

[25] *See supra* note 15.

[26] *See* CBOE's Fees Schedule and ISE's Fee Schedule.

[27] 15 U.S.C. 78s(b)(3)(A)(ii).

should refer to File Number SR–Phlx–2013–23, and should be submitted on or before April 26, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[28]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–07939 Filed 4–4–13; 8:45 am]

BILLING CODE 8011–01–P

[28] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Environmental Impact Statement: Cook County, Illinois

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Revised Notice of Intent.

SUMMARY: The FHWA is issuing this revised notice of intent to advise the public that an environmental impact statement is being prepared for the proposed I–290 highway improvement project in Cook County, Illinois, and that the project limits in the Notice of Intent (NOI) published in the **Federal Register** on February 26, 2010 have been expanded.

FOR FURTHER INFORMATION CONTACT: Mr. J. Michael Bowen, P.E., Acting Division Administrator, Federal Highway Administration, 3250 Executive Park Drive, Springfield, Illinois 62703, Phone: (217) 492–4600. John Fortmann, P.E., Acting Deputy Director of Highways, Acting Region One Engineer, District 1, Illinois Department of Transportation, 201 W. Center Court, Schaumburg, IL. 60196–1096, Phone: (847) 705–4110.

SUPPLEMENTARY INFORMATION: The FHWA, in cooperation with the Illinois Department of Transportation, is preparing an environmental impact statement (EIS) on a proposal to improve Interstate 290 (I–290) located in Cook County, Illinois. Based on public input and studies conducted to date, FHWA and IDOT now will include an additional section of I–290 from east of IL 50 (Cicero Avenue) to Racine Avenue in the EIS so that the limits of the proposed improvements are from west of Mannheim Road to Racine Avenue, a total distance of 13.0 miles. The additional section between east of Cicero Avenue and Racine Avenue may include operational improvements consisting of the potential conversion of two or more lanes of the eight lane expressway to accommodate managed lanes or various tolling strategies.

Improvements to the corridor are considered necessary due to safety concerns, operational issues, traffic congestion, and age of facility. Alternatives under consideration include (1) taking no action; (2) a full range of multi-modal build alternatives that involve reconstruction of all, or portions of, I–290 and the rehabilitation of the remainder to include operational changes.

Improvements to I–290 have the potential to affect environmental features in the project area depending on the alternative selected. The corridor is located in a highly developed mature urban setting with limited biological and natural resources. The built environment has the potential to be effected. Some features include: cemeteries, parks, special waste sites, nearby historic districts, possible residential and commercial displacements, sensitive noise receptors, a crossing of the Des Plaines River, and related indirect and cumulative impact considerations.

Letters have been sent to appropriate Federal, State, and local agencies reflecting the revised project limits, describing the proposed action, and soliciting comments. Input from Resource Agencies will continue to be obtained through the established stakeholder involvement methods including the Corridor Advisory Group (CAG) and NEPA/404 Merger process.

The Illinois Department of Transportation's Context Sensitive Solutions (CSS) process will continue to be used for public involvement. The existing Stakeholder Involvement Plan (SIP) will be updated to ensure that the full range of issues related to the change in project limits are identified and addressed. The SIP will continue to provide meaningful opportunities for all stakeholders to participate in defining transportation issues and solutions for the study area. The Corridor Advisory Group will continue as a primary method of stakeholder interaction. In addition, a public hearing and comment period will be held following the release of the Draft EIS. Public notice will be given for the time and place of the public hearing. A project Web site has been established (*www.eisenhowerexpressway.com)* as one element of the project public involvement process.

To ensure that the full range of issues related to this proposed action are addressed and all significant issues identified, comments and suggestions are invited from all interested parties. Comments or questions concerning this proposed action and the EIS should be directed to the FHWA at the address provided above.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Issued On: April 1, 2013.

J. Michael Bowen,

Acting Division Administrator, Springfield, Illinois.

[FR Doc. 2013–07936 Filed 4–4–13; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. AB 33 (Sub-No. 302X)]

Union Pacific Railroad Company—Abandonment Exemption—in Dunn County, WI.

Union Pacific Railroad Company (UP) filed a verified notice of exemption under 49 CFR part 1152 subpart F–*Exempt Abandonments* to abandon a 0.58-mile line of railroad on its Menomonie Industrial Lead from milepost 0.32 near Cedar Falls Road to the end of the line at milepost 0.90 near Oak Avenue, in Menomonie, Dunn County, Wis. (the Line). The Line traverses United States Postal Service Zip Code 54751.

UP has certified that: (1) No local traffic has moved over the Line for at least two years; (2) there is no overhead traffic on the Line; (3) no formal complaint filed by a user of rail service on the Line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the Line either is pending with the Surface Transportation Board (Board) or with any U.S. District Court or has been decided in favor of complainant within the two-year period; and (4) the requirements at 49 CFR 1105.7(c) (environmental report), 49 CFR 1105.11 (transmittal letter), 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to this exemption, any employee adversely affected by the abandonment shall be protected under *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho,* 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received, this exemption will be effective on May 7, 2013, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,[1] formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2),[2] and trail use/rail banking requests under 49 CFR 1152.29 must be filed by April 15, 2013. Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by April 25, 2013, with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001.[3]

A copy of any petition filed with the Board should be sent to UP's representative: Mack H. Shumate, Jr., Senior General Attorney, Union Pacific Railroad Company, 101 North Wacker Drive, Room 1920, Chicago, IL 60606.

If the verified notice contains false or misleading information, the exemption is void *ab initio*.

UP has filed a combined environmental and historic report that addresses the effects, if any, of the abandonment on the environment and historic resources. OEA will issue an environmental assessment (EA) by April 12, 2013. Interested persons may obtain a copy of the EA by writing to OEA (Room 1100, Surface Transportation Board, Washington, DC 20423–0001) or by calling OEA, at (202) 245–0305. Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at 1–800–877–8339. Comments on environmental and historic preservation matters must be filed within 15 days after the EA becomes available to the public.

Environmental, historic preservation, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Pursuant to the provisions of 49 CFR 1152.29(e)(2), UP shall file a notice of consummation with the Board to signify that it has exercised the authority granted and fully abandoned the Line. If consummation has not been effected by UP's filing of a notice of consummation by April 5, 2014, and there are no legal or regulatory barriers to consummation, the authority to abandon will automatically expire.

Board decisions and notices are available on our Web site at ''*www.stb.dot.gov*.''

Decided: April 2, 2013.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Raina S. White,

Clearance Clerk.

[FR Doc. 2013–08001 Filed 4–4–13; 8:45 am]

BILLING CODE 4915–01–P

[1] The Board will grant a stay if an informed decision on environmental issues (whether raised by a party or by the Board's Office of Environmental Analysis (OEA) in its independent investigation) cannot be made before the exemption's effective date. *See Exemption of Out-of-Serv. Rail Lines,* 5 I.C.C.2d 377 (1989). Any request for a stay should be filed as soon as possible so that the Board may take appropriate action before the exemption's effective date.

[2] Each OFA must be accompanied by the filing fee, which is currently set at $1,600. *See* 49 CFR 1002.2(f)(25).

[3] While UP does not believe that the Line's right-of-way is suitable for public purposes such as roads or highways or other forms of mass transportation, UP states that the right-of-way is suitable for conservation and use as a public hiking and bike trail, and indicates that it has negotiated a tentative agreement for such use with the City of Menomonie.

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Part II

Department of Commerce

National Oceanic and Atmospheric Administration

50 CFR Parts 223 and 224

Endangered and Threatened Wildlife and Plants; Proposed Endangered, Threatened, and Not Warranted Listing Determinations for Six Distinct Population Segments of Scalloped Hammerhead Sharks; Proposed Rule

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 223 and 224

[Docket No. 111025652–3245–02]

RIN 0648–XA798

Endangered and Threatened Wildlife and Plants; Proposed Endangered, Threatened, and Not Warranted Listing Determinations for Six Distinct Population Segments of Scalloped Hammerhead Sharks

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

ACTION: Proposed rule; request for comments.

SUMMARY: In response to a petition submitted by WildEarth Guardians and Friends of Animals to list the species as threatened or endangered, we, NMFS, have completed a comprehensive status review under the Endangered Species Act (ESA) for the scalloped hammerhead shark (*Sphyrna lewini*). Based on the best scientific and commercial information available, including the status review report (Miller *et al.,* 2013), and other information available since completion of the status review report, we have determined that the species is comprised of six distinct population segments (DPSs) that qualify as species under the ESA: Northwest Atlantic and Gulf of Mexico (NW Atlantic & GOM DPS); Central and Southwest Atlantic (Central & SW Atlantic DPS); Eastern Atlantic DPS; Indo-West Pacific DPS; Central Pacific DPS; and Eastern Pacific DPS. After reviewing the best available scientific and commercial information on the DPSs, we have determined that two DPSs warrant listing as endangered, the Eastern Atlantic and Eastern Pacific DPSs; two DPSs warrant listing as threatened, the Central & SW Atlantic and Indo-West Pacific DPSs; and two DPSs do not warrant listing at this time, the NW Atlantic & GOM DPS and the Central Pacific DPS. Any protective regulations determined to be necessary and advisable for the conservation of the threatened DPSs under ESA section 4(d) would be proposed in a subsequent **Federal Register** announcement. Should the proposed listings be finalized, we would also designate critical habitat for the species, to the maximum extent prudent and determinable. We solicit information to assist these listing determinations, the development of proposed protective regulations, and designation of critical habitat in the event these proposed DPSs are finally listed.

DATES: Comments on this proposed rule must be received by June 4, 2013. Public hearing requests must be requested by May 20, 2013.

ADDRESSES: You may submit comments on this document, identified by the code NOAA–NMFS–2011–0261 by any of the following methods:

- *Electronic Submissions:* Submit all electronic comments via the Federal eRulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2011-0261,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit written comments to Office of Protected Resources, NMFS, 1315 East-West Highway, Silver Spring, MD 20910.
- *Fax:* 301–713–4060, Attn: Maggie Miller

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (e.g., name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous). Attachments to electronic comments will be accepted in Microsoft Word, Excel, or Adobe PDF file formats only. The proposed rule and the status review report are also available electronically on the NMFS Web site at *http://www.nmfs.noaa.gov/pr/species/fish/scallopedhammerheadshark.htm.*

FOR FURTHER INFORMATION CONTACT: Maggie Miller, NMFS, Office of Protected Resources, (301) 427–8403.

SUPPLEMENTARY INFORMATION:

Background

On August 14, 2011, we received a petition from WildEarth Guardians and Friends of Animals to list the scalloped hammerhead shark (*Sphyrna lewini*) as threatened or endangered under the ESA throughout its entire range, or, as an alternative, to delineate the species into five DPSs (Eastern Central and Southeast Pacific, Eastern Central Atlantic, Northwest and Western Central Atlantic, Southwest Atlantic, and Western Indian Ocean) and list any or all of these DPSs as threatened or endangered. The petitioners also requested that critical habitat be designated for the scalloped hammerhead under the ESA. On November 28, 2011, we published a positive 90-day finding (76 FR 72891), announcing that the petition presented substantial scientific or commercial information indicating the petitioned action of listing the species may be warranted and explained the basis for that finding. We also announced the initiation of a status review of the species, as required by Section 4(b)(3)(a) of the ESA, and requested information to inform the agency's decision on whether the species warranted listing as endangered or threatened under the ESA.

Listing Species Under the Endangered Species Act

We are responsible for determining whether scalloped hammerhead sharks are threatened or endangered under the ESA (16 U.S.C. 1531 *et seq.*) To make this determination, we first consider whether a group of organisms constitutes a ''species'' under Section 3 of the ESA, then whether the status of the species qualifies it for listing as either threatened or endangered. Section 3 of the ESA defines species to include ''any subspecies of fish or wildlife or plants, and any distinct population segment of any species of vertebrate fish or wildlife which interbreeds when mature.'' On February 7, 1996, NMFS and the U.S. Fish and Wildlife Service (USFWS; together, the Services) adopted a policy describing what constitutes a DPS of a taxonomic species (61 FR 4722). The joint DPS policy identified two elements that must be considered when identifying a DPS: (1) The discreteness of the population segment in relation to the remainder of the species (or subspecies) to which it belongs; and (2) the significance of the population segment to the remainder of the species (or subspecies) to which it belongs. As stated in the joint DPS policy, Congress expressed its expectation that the Services would exercise authority with regard to DPSs sparingly and only when the biological evidence indicates such action is warranted.

Section 3 of the ESA defines an endangered species as ''any species which is in danger of extinction throughout all or a significant portion of its range'' and a threatened species as one ''which is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range.'' Thus,

in the context of the ESA, the Services interpret an ''endangered species'' to be one that is presently at risk of extinction. A ''threatened species,'' on the other hand, is not currently at risk of extinction, but is likely to become so in the foreseeable future. In other words, a key statutory difference between a threatened and endangered species is the timing of when a species may be in danger of extinction, either now (endangered) or in the foreseeable future (threatened). The statute also requires us to determine whether any species is endangered or threatened as a result of any one or a combination of the following five factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence (ESA, section 4(a)(1)(A)–(E)). Section 4(b)(1)(A) of the ESA requires us to make listing determinations based solely on the best scientific and commercial data available after conducting a review of the status of the species and after taking into account efforts being made by any State or foreign nation or political subdivision thereof to protect the species. In evaluating the efficacy of existing protective efforts, we rely on the Services' joint *Policy on Evaluation of Conservation Efforts When Making Listing Decisions* (''PECE''; 68 FR 15100; March 28, 2003). The PECE provides direction for consideration of conservation efforts that have not been implemented, or have been implemented but not yet demonstrated effectiveness.

Status Review

We convened a team of agency scientists to conduct the status review for the species and prepare a report. The status review report of the scalloped hammerhead shark (Miller *et al.,* 2013) compiles the best available information on the status of the scalloped hammerhead shark as required by the ESA, provides information on discreteness and significance of populations and potential DPSs, and assesses the current and future extinction risk for these scalloped hammerhead shark populations, focusing primarily on threats related to the five statutory factors set forth above. We appointed a contractor in the Office of Protected Resources Endangered Species Division to undertake a scientific review of the biology, population status and future outlook for the scalloped hammerhead shark. Next we convened a team of biologists and shark experts (Extinction Risk Analysis (ERA) team) to conduct an extinction risk analysis for the scalloped hammerhead shark populations, using the information in the scientific review. The ERA team was comprised of a fishery biologist from NMFS Office of Protected Resources, two fishery management specialists from NMFS' Highly Migratory Species Management Division, two research fishery biologists from NMFS' Southeast Fisheries Science Center and Pacific Island Fisheries Science Center, and a fishery biologist contractor with NMFS' Office of Protected Resources, with group expertise in shark biology and ecology, population dynamics, highly migratory species management, and stock assessment science. The status review report presents the ERA team's professional judgment of the extinction risk facing each population but makes no recommendation as to the listing status of each. The status review report is available electronically at *http://www.nmfs.noaa.gov/pr/species/fish/scallopedhammerheadshark.htm*.

The status review report was peer reviewed by three scientists with scalloped hammerhead shark expertise from academic institutions. The peer reviewers were asked to evaluate the adequacy, appropriateness, and application of data used in the Status Review document as well to evaluate the findings made in the ''Assessment of Extinction Risk'' section of the report. We subsequently reviewed the status review report, its cited references, and peer review comments, and believe the status review report, upon which this proposed rule is based, provides the best available scientific and commercial information on the scalloped hammerhead shark. Much of the information discussed below on scalloped hammerhead shark biology, distribution, abundance, threats, and extinction risk is attributable to the status review report. However, we have independently applied the statutory provisions of the ESA, including evaluation of the factors set forth in Section 4(a)(1)(A)–(E); our regulations regarding listing determinations; and our DPS policy in making the proposed listing determinations.

Life History, Biology, and Status of the Petitioned Species

Taxonomy and Species Description

All hammerhead sharks belong to the family Sphyrnidae and are classified as ground sharks (Order Carcharhiniformes). Most hammerheads belong to the Genus *Sphyrna* with one exception, the winghead shark (*E. blochii*), which is the sole species in the Genus *Eusphyra.* The hammerhead sharks are recognized by their laterally expanded head that resembles a hammer, hence the common name ''hammerhead.'' The scalloped hammerhead shark (*Sphyrna lewini*) is distinguished from other hammerheads by a marked central indentation on the anterior margin of the head, along with two more indentations on each side of this central indentation, giving the head a ''scalloped'' appearance. It has a broadly arched mouth and the rear margin of the head is slightly swept backward. The dentition of the hammerhead consists of small, narrow, and triangular teeth with smooth edges (often slightly serrated in larger individuals), and is similar in both jaws. The front teeth are erect while subsequent teeth have oblique cusps, and the lower teeth are more erect than the upper teeth (Bester, n.d.).

The body of the scalloped hammerhead is fusiform, with a large first dorsal fin and low second dorsal and pelvic fins. The first dorsal fin is moderately hooked with its origin over or slightly behind the pectoral fin insertions and the rear tip in front of the pelvic fin origins. The height of the second dorsal fin is less than the anal fin height and has a posterior margin that is approximately twice the height of the fin, with the free rear tip almost reaching the precaudal pit. The pelvic fins have relatively straight rear margins while the anal fin is deeply notched on the posterior margin (Compagno, 1984). The scalloped hammerhead shark generally has a uniform gray, grayish brown, bronze, or olive coloration on top of the body that shades to white on the underside with dusky or black pectoral fin tips.

Current Distribution

The scalloped hammerhead shark can be found in coastal warm temperate and tropical seas worldwide. In the western Atlantic Ocean, the scalloped hammerhead range extends from the northeast coast of the United States (from New Jersey to Florida) to Brazil, including the Gulf of Mexico and Caribbean Sea. In the eastern Atlantic, it can be found from the Mediterranean to Namibia. Populations in the Indian Ocean are found in the following locations: South Africa and the Red Sea to Pakistan, India, and Myanmar, and in the western Pacific the scalloped hammerhead can be found from Japan and China to New Caledonia, including throughout the Philippines, Indonesia, and off Australia. Distribution in the

eastern Pacific Ocean extends from the coast of southern California (U.S.), including the Gulf of California, to Ecuador and possibly Peru (Compagno, 1984), and off waters of Hawaii (U.S.) and Tahiti. The scalloped hammerhead shark occurs over continental and insular shelves, as well as adjacent deep waters, but is seldom found in waters cooler than 22° C (Compagno, 1984; Schulze-Haugen and Kohler, 2003). It ranges from the intertidal and surface to depths of up to 450–512 m (Sanches, 1991; Klimley, 1993), with occasional dives to even deeper waters (Jorgensen *et al.,* 2009). It has also been documented entering enclosed bays and estuaries (Compagno, 1984).

Movement and Habitat Use

Scalloped hammerhead sharks are highly mobile and partly migratory and are likely the most abundant of the hammerhead species (Maguire *et al.,* 2006). These sharks have been observed making primarily short-distance migrations along continental margins as well as between oceanic islands in tropical waters, with tagging studies revealing the tendency for scalloped hammerhead sharks to aggregate around and travel to and from core areas or ''hot spots'' within locations (Holland *et al.,* 1993; Kohler and Turner, 2001; Duncan and Holland, 2006; Hearn *et al.,* 2010; Bessudo *et al.,* 2011; Diemer *et al.,* 2011). However, scalloped hammerhead sharks are also capable of traveling long distances (1,941 km, Bessudo *et al.,* 2011; 1,671 km, Kohler and Turner, 2001; Hearn *et al.,* 2010), and in many of these tagging studies the sharks were tracked leaving the study area for long periods of time, ranging from 2 weeks to several months (Hearn *et al.,* 2010; Bessudo *et al.,* 2011) to almost a year (324 days) (Duncan and Holland, 2006) before eventually returning, displaying a level of site fidelity to these areas.

Both juveniles and adult scalloped hammerhead sharks occur as solitary individuals, pairs, or in schools. The schooling behavior has been documented during summer migrations off the coast of South Africa as well as in permanent resident populations, like those in the East China Sea (Compagno, 1984). Adult aggregations are most common offshore over seamounts and near islands, especially near the Galapagos, Malpelo, Cocos and Revillagigedo Islands, and within the Gulf of California (Compagno, 1984; CITES, 2010; Hearn *et al.,* 2010; Bessudo *et al.,* 2011). Neonate and juvenile aggregations are more common in nearshore nursery habitats, such as Kāne'ohe Bay in Oahu, Hawaii, coastal waters off Oaxaca, Mexico, and Guam's inner Apra Harbor (Duncan and Holland, 2006; Bejarano-Álvarez *et al.,* 2011). It has been suggested that juveniles inhabit these nursery areas for up to or more than a year, as they provide valuable refuges from predation (Duncan and Holland, 2006).

Diet

The scalloped hammerhead shark is a high trophic level predator (trophic level = 4.1; Cortés, 1999) and opportunistic feeder with a diet that includes a wide variety of teleosts, cephalopods, crustaceans, and rays (Compagno, 1984; Bush, 2003; Júnior *et al.,* 2009; Noriega *et al.,* 2011). In a study on feeding behavior in Kāne'ohe Bay, Bush (2003) found a nocturnal increase in the rate of foraging by juvenile scalloped hammerheads, with sharks consuming a mixture of crustaceans and teleosts. The alpheid and goby species were the most important prey items in their diet. Off the coast of Brazil, immature *S. lewini* frequently fed on reef and pelagic fish, as well as cephalopod species (*Chiroteuthis* sp. and *Vampyroteuthis infernalis*) that inhabit deep waters (Júnior *et al.,* 2009). Stomachs of 466 *S. lewini* off the coast of Australia revealed the importance of bony fish as a prey item, followed by elasmobranchs, octopus and squid, and baitfish, with a positive correlation between shark length and the proportion of elasmobranchs in stomach contents (Noriega *et al.,* 2011).

Reproduction

The scalloped hammerhead shark is viviparous (i.e., give birth to live young), with a gestation period of 9–12 months (Branstetter, 1987; Stevens and Lyle, 1989), which may be followed by a one-year resting period (Liu and Chen, 1999). Females attain maturity around 200–250 cm total length (TL) while males reach maturity at smaller sizes (range 128–200 cm TL). Estimates of age at maturity vary by region, ranging from 3.8 to 15.2 years, but are likely a result of differences in band interpretations in aging methodology approaches (Piercy *et al.,* 2007). Parturition, however, does not appear to vary by region and may be partially seasonal (Harry *et al.,* 2011), with neonates present year round but with abundance peaking during the spring and summer months (Duncan and Holland, 2006; Adams and Paperno, 2007; Bejarano-Álvarez *et al.,* 2011; Harry *et al.* 2011; Noriega *et al.,* 2011). Females move inshore to birth, with litter sizes anywhere between 1 and 41 live pups. Off the coast of northeastern Australia, Noriega *et al.* (2011) found a positive correlation between litter size and female shark length for scalloped hammerheads, as did White *et al.* (2008) in Indonesian waters. However, off the northeastern coast of Brazil, Hazin *et al.* (2001) found no such relationship.

Growth

Total length at birth estimates range from 313 mm TL (Chen *et al.,* 1990) to 570 mm TL (White *et al.,* 2008). Duncan and Holland (2006) calculated an early juvenile growth rate of 9.6 cm per year. Observed maximum sizes for male scalloped hammerheads range from 196–321 cm TL, with the oldest male scalloped hammerhead estimated at 30.5 years (Piercy *et al.,* 2007). Observed maximum sizes for female scalloped hammerheads range from 217–346 cm TL, with the oldest female scalloped hammerhead estimated at 31.5 years (Kotas *et al.,* 2011). Estimates of the von Bertalanffy growth parameters vary by study, location, and sex of the animal, with the following ranges: L_∞ = 212 to 519 cm TL, k = 0.05 to 0.25 year^{-1}, t_0 = −3.9 to −0.4 (see Miller *et al.,* 2013).

The life history of the scalloped hammerhead shark, like most elasmobranchs, is characterized as long lived (at least 20–30 years), late maturing, and relatively slow growing (based on Branstetter (1990), where k < 0.1/year indicates slow growth for sharks), which generally contributes to a low intrinsic rate of increase. Using life history parameters from the Atlantic *S. lewini* populations, estimates of the intrinsic rate of increase (r) for the scalloped hammerhead shark range from 0.028 (Smith *et al.,* 1998) to 0.157 (Cortés *et al.,* 2010). Based on the Food and Agriculture Organization of the United Nations (FAO) productivity indices for exploited fish species (where r < 0.14 is considered low productivity), overall estimates of (r) values for the scalloped hammerhead shark indicate that *S. lewini* populations are generally vulnerable to depletion and may be slow to recover from overexploitation.

Current Status

Scalloped hammerhead sharks can be found worldwide, with no present indication of a range contraction. The oldest living *S. lewini* populations are found in the central Indo-West Pacific, indicating this region as the origin of the species (Duncan *et al.,* 2006; Daly-Engel *et al.,* 2012). During the late Pleistocene period, *S. lewini* underwent several dispersal events (Duncan *et al.,* 2006). Following the closing of the Isthmus of Panama, it was suggested that gene flow occurred from west to east, with *S. lewini* traveling from the Atlantic Ocean into the Indo-Pacific, via southern Africa (Duncan *et al.,* 2006).

Scalloped hammerhead sharks are both targeted and taken as bycatch in many global fisheries, with their fins a primary product for international trade. To a much lesser extent, scalloped hammerhead sharks are also caught for their meat (with Colombia, Kenya, Mexico, Mozambique, Philippines, Seychelles, Spain, Sri Lanka, China (Taiwan), Tanzania, and Uruguay identified as countries that consume hammerhead meat (Vannuccini, 1999; CITES, 2010)). However, given the fact that the meat is essentially unpalatable, due to its high urea concentration, it is thought that current volume of *S. lewini* traded meat and products is insignificant when compared to the volume of *S. lewini* fins in international trade (CITES, 2010). Unfortunately, the lack of species-specific reporting in these trade products, as well as the scarcity of information on the fisheries catching scalloped hammerhead sharks prior to the early 1970s, with only occasional mentions in historical records, makes it difficult to assess the current worldwide scalloped hammerhead shark status.

In 2007, the International Union for Conservation of Nature (IUCN) considered the scalloped hammerhead shark to be endangered globally, based on an assessment by Baum *et al.* (2007) and its own criteria (A2bd and 4bd), and placed the species on its ''Red List.'' Under criteria A2bd and 4bd, a species may be classified as endangered when its ''observed, estimated, inferred or suspected'' population size is reduced by 50% or more over the last 10 years, any 10 year time period, or three generation period, whichever is the longer, and where the causes of reduction may not have ceased, be understood, or be reversible based on an index of abundance appropriate to the taxon and/or the actual or potential levels of exploitation. IUCN justification for the categorization includes both species-specific estimates and estimates for the entire hammerhead family that suggest declines in abundance of 50–90 percent over time periods of up to 32 years in various regions of the species' range. The IUCN inferred similar declines in areas where species-specific data are unavailable, but where there is evidence of substantial fishing pressure on the scalloped hammerhead shark. As a note, the IUCN classification for the scalloped hammerhead shark alone does not provide the rationale for a listing recommendation under the ESA, but the sources of information that the classification is based upon are evaluated in light of the standards on extinction risk and impacts or threats to the species.

Identification of Distinct Population Segments

As described above, the ESA's definition of ''species'' includes ''any subspecies of fish or wildlife or plants, and any distinct population segment of any species of vertebrate fish or wildlife which interbreeds when mature.'' The genetic diversity among subpopulations, geographic isolation, and differences in international regulatory mechanisms provide evidence that several populations of scalloped hammerhead sharks meet the DPS Policy criteria. Therefore, prior to evaluating the conservation status for scalloped hammerhead sharks, and in accordance with the joint DPS policy, we considered: (1) The discreteness of any scalloped hammerhead shark population segment in relation to the remainder of the subspecies to which it belongs; and (2) the significance of any scalloped hammerhead shark population segment to the remainder of the subspecies to which it belongs.

Discreteness

The Services' joint DPS policy states that a population of a vertebrate species may be considered discrete if it satisfies either one of the following conditions: (1) It is markedly separated from other populations of the same taxon as a consequence of physical, physiological, ecological, or behavioral factors (quantitative measures of genetic or morphological discontinuity may provide evidence of this separation) or (2) it is delimited by international governmental boundaries within which differences in control of exploitation, management of habitat, conservation status, or regulatory mechanisms exist that are significant in light of Section 4(a)(1)(D) of the ESA. To inform its decisions with respect to possible scalloped hammerhead DPSs, the ERA team mainly relied on genetic data, tagging studies, and evidence of differences in the control of exploitation and management by international governmental bodies.

Although scalloped hammerhead sharks are highly mobile, this species rarely conducts trans-oceanic migrations (Kohler and Turner, 2001; Duncan and Holland, 2006; Duncan *et al.,* 2006; Chapman *et al.,* 2009; Diemer *et al.,* 2011). Female scalloped hammerhead sharks may even display a level of site fidelity for reproduction purposes (Duncan *et al.,* 2006; Chapman *et al.,* 2009) that likely contributes to the apparent genetic discontinuity in the global scalloped hammerhead shark population (Duncan *et al.,* 2006; Chapman *et al.,* 2009; Daly-Engel *et al.,* 2012). Genetics analyses for scalloped hammerhead sharks using mitochondrial DNA (mtDNA), which is maternally inherited, and microsatellite loci data, which reflects the genetics of both parents, have consistently shown that scalloped hammerhead subpopulations are genetically diverse and that individual subpopulations can be differentiated, especially those populations separated by ocean basins (Duncan *et al.,* 2006; Chapman *et al.,* 2009; Ovenden *et al.,* 2011; Daly-Engel *et al.,* 2012). Using mtDNA samples, Duncan *et al.* (2006) discovered no sharing of haplotypes between *S. lewini* in the Atlantic and those from the Pacific or Indian Ocean, proving genetic isolation by oceanic barriers. Chapman *et al.* (2009) further substantiated this finding in a subsequent examination of mtDNA from scalloped hammerhead shark fins, confirming the absence of shared haplotypes between *S. lewini* in the western Atlantic (n = 177) and those found in the Indo-Pacific (n = 275). Using microsatellite loci from 403 *S. lewini* samples, Daly-Engel et al. (2012) concluded that scalloped hammerhead sharks in the western and eastern Atlantic Ocean were significantly differentiated from other populations in the Pacific and Indian Oceans, suggesting that the male sharks in the Atlantic Ocean rarely mix with scalloped hammerheads found elsewhere in the world.

Atlantic Ocean Population Segments

Further delineation within ocean basins is supported by regional and global genetic studies as well as tagging data. For example, in the Atlantic, both mitochondrial and microsatellite data indicate genetic discontinuity within this ocean basin, with distinct populations of scalloped hammerhead sharks defined by their respective coasts. Analysis of *S. lewini* haplotypes from samples taken off West Africa and the East Coast of the United States reveal genetic separation of these two populations and point to missing hypothetical ancestors (Duncan *et al.,* 2006). Using biparentally-inherited DNA, Daly-Engel *et al.* (2012) also provided evidence of genetic structure across the Atlantic Ocean, with scalloped hammerhead samples from West Africa weakly differentiated from South Carolina samples ($F_{ST} = 0.052$, $0.05 \geq P \geq 0.01$) and significantly differentiated from Gulf of Mexico samples ($F_{ST} = 0.312$, $P \leq 0.001$). These studies confirm the genetic isolation of the eastern and western Atlantic scalloped hammerhead populations,

which should be treated as separate and discrete populations (Chapman personal communication, 2012).

Finer scale delineation within the western Atlantic population is also warranted based on analysis of both maternally and bi-parentally inherited DNA; however, the boundaries of this delineation are unresolved. For example, Chapman *et al.* (2009) structured the western Atlantic scalloped hammerhead population into three distinct mitochondrial stocks: the northern (U.S. Atlantic and Gulf of Mexico), central (Central American Caribbean), and southern (Brazil) stocks. Daly-Engel *et al.* (2012), on the other hand, found significant population differentiation in between the Gulf of Mexico and the nearby South Carolina site in the western Atlantic ($F_{ST} = 0.201$, $P < 0.001$) using microsatellite fragments. This finding contrasts with Chapman *et al.* (2009) who did not find significant population differentiation between *S. lewini* in the U.S. Atlantic and the Gulf of Mexico, and Duncan *et al.* (2006) who found a lack of genetic structure along continental margins using mtDNA samples. Thus, although the genetic data support dividing the western Atlantic population into subpopulations, there is disagreement on where the lines should be drawn.

Since differences in genetic composition can sometimes be explained by the behavior of a species, the ERA team examined tagging data to learn more about the movements of the scalloped hammerhead populations along the western Atlantic coast. The available data corroborate the genetic findings that these populations of scalloped hammerhead sharks rarely travel long distances. In fact, the median distance between mark and recapture of 3,278 adult scalloped hammerhead sharks, tagged along the eastern U.S. coast and Gulf of Mexico, was less than 100 km (Kohler and Turner, 2001). In addition, none of these tagged sharks were tracked moving south (Kohler personal communication, 2012), indicating a potential separation of the northwest Atlantic and Gulf of Mexico population from the Central and South American population based on movement behavior (Kohler personal communication, 2012).

To further inform its decisions as to whether there is discreteness amongst the western Atlantic scalloped hammerhead subpopulations, the ERA team looked at possible differences in current conservation status and regulatory mechanisms across international boundaries. In the northwest Atlantic and Gulf of Mexico, the United States has implemented strict regulations aimed at controlling the exploitation of the sharks, including the scalloped hammerhead, with the development of fishery management plans (FMPs), requirement for stock assessments, and quota monitoring. On August 29, 2011, NMFS prohibited the taking of scalloped hammerhead sharks by the U.S. commercial highly migratory species (HMS) pelagic longline fishery and recreational fisheries for tunas, swordfish, and billfish in the Atlantic Ocean, including the Caribbean Sea and Gulf of Mexico (76 FR 53652; August 29, 2011). These comprehensive regulatory mechanisms are expected to help protect *S. lewini* in the northwest Atlantic and Gulf of Mexico. Although the U.S. regulations extend to the U.S. economic exclusive zone (EEZ) in the Caribbean (i.e., surrounding U.S. territories), the vast majority of the Caribbean sea, as well as waters farther south, lack regulatory measures controlling the exploitation of scalloped hammerheads. For example, Brazil, a country that has seen declines of 80 percent or more in catch per unit effort (CPUE) of scalloped hammerheads in various fisheries (FAO, 2010), does not have regulations specific to scalloped hammerhead sharks or quota monitoring of the species. Many countries in Central America are also either lacking protections for shark species or have major problems with enforcement of their respective fishery regulations (Kyne *et al.,* 2012). Thus, the species continues to be heavily fished for by industrial and artisanal fishers in waters off Central and South America. Due to these differences in control of exploitation and regulatory mechanisms for management and conservation of this species across international boundaries, and coupled with the results from the genetic analyses and tagging studies, the ERA team concluded that the western Atlantic population is, in fact, two discrete subpopulations: the Northwest Atlantic & Gulf of Mexico population and the Central & Southwest Atlantic population. We find both of these population segments satisfy the discreteness criterion under the DPS policy.

Indo-West Pacific Population Segments

Within the Indo-West Pacific region, a lack of genetic structure suggests frequent mixing of scalloped hammerhead populations found in these waters (Daly-Engel *et al.,* 2012). A comparison of microsatellite loci samples from the Indian Ocean, specifically samples from the Seychelles and West Australia, as well as from South Africa and West Australia, indicated either no or weak population differentiation (Daly-Engel *et al.,* 2012). Additionally, there was no evidence of genetic structure between the Pacific and Indian Oceans, as samples from Taiwan, Philippines, and East Australia in the western Pacific showed no population differentiation from samples in the Indian Ocean ($F_{ST} = -0.018$, $P = 0.470$) (Daly-Engel *et al.,* 2012). Although these genetic data may imply that males of the species move widely within this region, potentially across ocean basins, tagging studies suggest otherwise. Along the east coast of South Africa, for example, *S. lewini* moved an average distance of only 147.8 km (data from 641 tagged scalloped hammerheads; Diemer *et al.,* 2011). Tagging studies in other regions also suggest limited distance movements, and only along continental margins, coastlines, or between islands with similar oceanographic conditions (Kohler and Turner, 2001; Duncan and Holland, 2006; Bessudo *et al.,* 2011). Thus, it seems more likely that the high connectivity of the habitats found along the Indian and western Pacific coasts has provided a means for this shark population to mix and reproduce without having to traverse deep ocean basins. In fact, along the east coast of Australia, Ovenden *et al.* (2011) found evidence of only one genetic stock of *S. lewini.* The samples, spanning almost 2,000 km of coastline on Australia's east coast, showed genetic homogeneity based on eight microsatellite loci and mtDNA markers, suggesting long-shore dispersal and panmixia of scalloped hammerhead sharks (Ovenden *et al.,* 2011). No genetic subdivision existed between Indonesia and the eastern or northern coasts of Australia, suggesting this species may move widely between the connecting habitats of Australia and Indonesia (Ovenden *et al.,* 2009; Ovenden *et al.,* 2011).

Although the aforementioned genetic analyses suggest males of the Indo-West Pacific population appear to make longer distance coastal movements than what the Atlantic subpopulations typically exhibit (Daly-Engel *et al.,* 2012), they have not been observed mixing with the neighboring eastern Atlantic population of sharks. The significant levels of genetic structure between *S. lewini* microsatellite samples from South Africa and those from West Africa samples ($F_{ST} = 0.07$, $P \leq 0.01$) corroborate this finding, with the number of migrants moving between these two locations estimated at 0.06 to 0.99 per generation (Daly-Engel *et al.,* 2012). Thus, although connected by a continuous coastline, the genetic data

indicate that the eastern Atlantic population and Indo-West Pacific populations rarely mix and qualify as discrete populations due to these genetic differences.

Pacific Ocean Population Segments

In addition to the Indo-West Pacific population, the ERA team found evidence of two other possible subpopulations of scalloped hammerheads in the Pacific Ocean: those common in the Central Pacific region and those found in the East Pacific region. The Central Pacific subpopulation of scalloped hammerheads appears to be markedly separate from other *S. lewini* populations within the Pacific Ocean as a consequence of physical and genetic factors. The Central Pacific population is located in the middle of the Pacific Ocean. Their range primarily encompasses the Hawaiian Archipelago, which includes the inhabited main islands in the southeast as well as the largely uninhabited Papahānaumokuākea Marine National Monument that extends from Nihoa to Kure Atoll in the northwest. Johnston Atoll is also included in this population's range due to its proximity to the Hawaiian Archipelago. In order to reach the other neighboring populations in the western and eastern Pacific, the Central Pacific scalloped hammerhead sharks would have to travel over hundreds to thousands of kilometers, overcoming various bathymetric barriers. However, as previously mentioned, tagging studies and mtDNA analyses suggest this species rarely makes long-distance oceanic migrations. Instead, the data support the assumption that this species more commonly disperses along continuous coastlines, continental margins, and submarine features, such as chains of seamounts, commonly associated with scalloped hammerhead shark ''hotspots'' (Holland *et al.,* 1993; Kohler and Turner, 2001; Duncan and Holland, 2006; Hearn *et al.,* 2010; Bessudo *et al.,* 2011; Diemer *et al.,* 2011). This is true even for island populations, with tagged *S. lewini* individuals frequently migrating to nearby islands and mainlands (Duncan and Holland, 2006; Hearn *et al.,* 2010; Bessudo *et al.,* 2011), but no evidence or data to support oceanic migration behavior.

For example, Bessudo *et al.* (2011) observed scalloped hammerhead sharks in the Eastern Tropical Pacific (ETP) and noted that although they are capable of covering long distances (i.e., 1941 km), the sharks remain within the area, moving widely around and occasionally between neighboring islands with similar oceanographic conditions. A study conducted in a nursery ground in Hawaii revealed that sharks travelled as far as 5.1 km in the same day, but the mean distance between capture points was only 1.6 km (Duncan and Holland, 2006). Another tagging study in Hawaii indicates that adult males remain ''coastal'' within the archipelago (Holland personal communication, 2012). The genetic data from scalloped hammerhead populations also supports this theory of limited oceanic dispersal, with significant genetic discontinuity associated with oceanic barriers but less so along continental margins (Duncan *et al.,* 2006; Chapman *et al.,* 2009; Daly-Engel *et al.,* 2012). With regards to the *S. lewini* sharks in Central Pacific and Eastern Pacific, both microsatellite loci and mtDNA data indicate significant genetic differentiation between these two populations (Daly-Engel *et al.,* 2011), corroborating the theory of genetic isolation due to biogeographic barriers. Thus, these genetic analyses, coupled with the tagging studies, suggest that the populations of scalloped hammerhead sharks found in the Pacific (i.e. Indo-West Pacific, Central Pacific, and East Pacific subpopulations) rarely conduct open ocean migrations (Kohler and Turner, 2001; Bessudo *et al.,* 2011; Diemer *et al.,* 2011; Holland personal communication, 2012) to mix or reproduce with each other.

Further separating these subpopulations, especially the Central Pacific scalloped hammerhead population from its neighboring western and eastern Pacific populations, are the differences in fisheries regulations across these international boundaries. The Central Pacific currently has many management controls in place that protect important scalloped hammerhead habitats and nursery grounds, as well as fishing regulations that control the exploitation of the species. For example, the fisheries of the Hawaiian Islands are managed by both Federal regulations, such as the Magnuson-Stevens Fishery Conservation and Management Act (MSA), and state regulations aimed at protecting and conserving marine resources. Currently, there are no directed shark fisheries in Hawaii; however, scalloped hammerheads are sometimes caught as bycatch on Hawaiian longline gear. The Hawaii pelagic longline (PLL) fishery, which operates mainly in the Northern Central Pacific Ocean, is managed through a Fishery Ecosystem Plan (FEP) developed by the Western Pacific Regional Fishery Management Council (WPFMC) and approved by NMFS under the authority of the MSA. In an effort to reduce bycatch in this fishery, a number of gear regulations and fishery management measures have been implemented. For example, a 50–75 nm (92.6–138.9 km) longline fishing buffer zone exists around the Hawaiian Islands, helping to protect scalloped hammerheads from being caught near popular nursery grounds and their coastal adult habitat. Periodic closures and effort limits in the shallow-set sector of this fishery (which has a higher shark catch rate) also helps protect scalloped hammerheads in this fishery.

In addition, mandatory fishery observers have been monitoring both sectors (shallow and deep) of the limited-entry Hawaii-based PLL fishery since 1994, with observer coverage increasing in recent years to provide a more comprehensive bycatch dataset. Shark finning, a practice which involves harvesting sharks, severing their fins and returning their remaining carcasses to the sea, was banned in 2000 for the Hawaii-based longline fishery. Additionally, the U.S. Shark Conservation Act of 2010 requires that sharks lawfully harvested in Federal waters, including those located in the range of this DPS, be landed with their fins naturally attached, and additional legislation aimed at shark finning was enacted in 2010 by the State of Hawaii (State of Hawaii SB2169). In the neighboring ETP, as well as other islands and countries in the western Pacific, regulatory mechanisms are either missing, inadequate, or weakly enforced, and illegal fishing is widespread. Therefore, it is reasonable to assume that the differences in the control of exploitation and regulatory mechanisms between the Central Pacific and the surrounding countries could influence the conservation status of the scalloped hammerhead population around the Central Pacific region and thus could be considered a discrete population under the DPS policy.

In the eastern Pacific region, results from both microsatellite loci data and mtDNA confirm the genetic isolation of the eastern Pacific *S. lewini* population from those found in the central and western Pacific, Indian, and Atlantic Oceans ($P \leq 0.001$) (Daly-Engel *et al.,* 2012). Nance *et al.* (2011) suggested that the ETP *S. lewini* population may actually exist as a series of small and genetically separate populations. This observed low genetic diversity in the eastern Pacific population may indicate peripatric speciation (i.e., formation of new species in isolated peripheral populations that are much smaller than

the original population) from the Indo-West Pacific hammerhead population (Duncan *et al.,* 2006). Interestingly, when compared to samples from the Gulf of Mexico, Daly-Engel *et al.* (2012) found high levels of allelic differentiation ($F_{ST} = 0.519$, $P \leq 0.001$), suggesting that these two populations have never mixed and thus make up the opposing ends of the *S. lewini* dispersal range from the Indo-West Pacific. The genetic differentiation and geographic isolation of the Eastern Pacific population from other scalloped hammerhead populations thus qualify it as a discrete population under the DPS policy.

Based on the above information on scalloped hammerhead population structuring, as well as additional information provided in the status review report, we have concluded that the following six discrete subpopulations of scalloped hammerhead sharks are present in the world: (1) Northwest Atlantic & Gulf of Mexico population segment, (2) Central & Southwest Atlantic population segment, (3) Eastern Atlantic population segment, (4) Indo-West Pacific population segment, (5) Central Pacific population segment, and (6) Eastern Pacific population segment. Each is markedly separate from the other five population segments as a consequence of genetic and/or physical factors, with some population segments also delimited by international governmental boundaries within which differences in control of exploitation, conservation status, or regulatory mechanisms exist that are significant in light of Section 4(a)(1)(D) of the ESA.

Significance

When the discreteness criterion is met for a potential DPS, as it is for the Northwest Atlantic & Gulf of Mexico, Central & Southwest Atlantic, Eastern Atlantic, Indo-West Pacific, Central Pacific, and Eastern Pacific population segments identified above, the second element that must be considered under the DPS policy is significance of each DPS to the taxon as a whole. Significance is evaluated in terms of the importance of the population segment to the overall welfare of the species. Some of the considerations that can be used to determine a discrete population segment's significance to the taxon as a whole include: (1) Persistence of the population segment in an unusual or unique ecological setting; (2) evidence that loss of the population segment would result in a significant gap in the range of the taxon; and (3) evidence that the population segment differs markedly from other populations of the species in its genetic characteristics.

Based on the results from the genetic and tagging analyses mentioned previously, we believe that there is evidence that loss of any of the population segments would result in a significant gap in the range of the taxon. For example, the Indo-West Pacific region, which is hypothesized as the center of origin for *S. lewini,* with the oldest extant scalloped hammerhead species found in this region (Duncan *et al.,* 2006; Daly-Engel *et al.,* 2012), covers a wide swath of the scalloped hammerhead sharks' range (extending from South Africa to Japan, and south to Australia and New Caledonia and neighboring Island countries). However, as Daly-Engel *et al.* (2012) notes, the migration rate of *S. lewini* individuals from West Africa into South Africa is very low (0.06 individuals per generation), suggesting that in the case of an Indo-West Pacific extirpation, re-colonization from the Eastern Atlantic to the Western Indian Ocean is very unlikely. In addition, re-colonization from the Central Pacific DPS would also occur rather slowly (on an evolutionary timescale) as those individuals would have to conduct trans-oceanic migrations, a behavior that has yet to be documented in this species. The Central Pacific region, itself (extending from Kure Atoll to Johnston Atoll, and including the Hawaiian Archipelago), encompasses a vast portion of the scalloped hammerhead sharks' range in the Pacific Ocean and is isolated from the neighboring Indo-West Pacific and eastern Pacific regions by deep expanses of water. Loss of this DPS would result in a decline in the number of suitable and productive nursery habitats and create a significant gap in the range of this taxon across the Pacific Ocean. From an evolutionary standpoint, the Central Pacific population is thought to be the ''stepping stone'' for colonization to the isolated ETP, as Duncan *et al.* (2006) observed two shared haplotypes between Hawaii and the otherwise isolated ETP population. In other words, in the case of an ETP extirpation and loss of the Central Pacific population, it would require two separate and rare colonization events to repopulate the ETP population: one for the re-colonization of the Central Pacific and another for the re-colonization of the ETP. Thus, on an evolutionary timescale, loss of the Central Pacific population would result in a significant truncation in the range of the taxon.

Even those discrete population segments that share a connecting coastline, like the Northwest Atlantic & Gulf of Mexico and Central & Southwest Atlantic population segments, will not likely see individuals re-colonizing the other population segment, given that gene flow is low between these areas and tagging studies show limited distance movements by individuals along the western Atlantic coast. In addition, repopulation by individuals from the eastern Pacific to the western Atlantic, or vice versa, is highly unlikely as these animals would have to migrate through suboptimal oceanographic conditions, such as very cold waters, that are detrimental to this species' survival. Therefore, the display of weak philopatry and constrained migratory movements provides evidence that loss of any of the discrete population segments would result in a significant gap in the range of the scalloped hammerhead shark, negatively impacting the species as a whole.

In summary, the scalloped hammerhead shark population segments considered by the ERA team meet both the discreteness and significance criterion of the DPS policy. We concur with the ERA team's conclusion that there are six scalloped hammerhead shark DPSs, which comprise the global population, and are hereafter referred to as: (1) NW Atlantic & GOM DPS, (2) Central & SW Atlantic DPS, (3) Eastern Atlantic DPS, (4) Indo-West Pacific DPS, (5) Central Pacific DPS, and (6) Eastern Pacific DPS. The boundaries for each of these DPSs, as determined from the DPS analysis, are as follows (see Figure 1):

(1) NW Atlantic & GOM DPS—Bounded to the north by 40° N. latitude (lat.), includes all U.S. EEZ waters in the Northwest Atlantic and extends due east along 28° N. lat. off the coast of Florida to 30° W. longitude (long.). In the Gulf of Mexico, the boundary line includes all waters of the Gulf of Mexico, with the eastern portion bounded by the U.S. and Mexico EEZ borders.

(2) Central & SW Atlantic DPS—Bounded to the north by 28° N. lat., to the east by 30° W. long., and to the south by 36° S. lat. All waters of the Caribbean Sea are within this DPS boundary, including the Bahamas' EEZ off the coast of Florida as well as Cuba's EEZ.

(3) Eastern Atlantic DPS—Bounded to the west by 30° W. long., to the north by 40° N. lat., to the south by 36° S. lat., and to the east by 20° E. long., but includes all waters of the Mediterranean Sea.

(4) Indo-West Pacific DPS—Bounded to the south by 36° S. lat., to the west by 15° E. long., and to the north by 40° N. lat. In the east, the boundary line extends from 175° W. long. due south to 10° N. lat., then due east along 10° N.

lat. to 140° W. long., then due south to 4° S. lat., then due east along 4° S. lat. to 130° W. long, and then extends due south along 130° W. long.

(5) Central Pacific DPS—Bounded to the north by 40° N lat., to the east by 140° W. long., to the south by 10° N. lat., and to the west by 175° E. long.

(6) Eastern Pacific DPS—bounded to the north by 40° N lat. and to the south by 36° S lat. The western boundary line extends from 140° W. long. due south to 10° N., then due west along 10° N. lat. to 140° W. long., then due south to 4° S. lat., then due east along 4° S. lat. to 130° W. long, and then extends due south along 130° W. long.

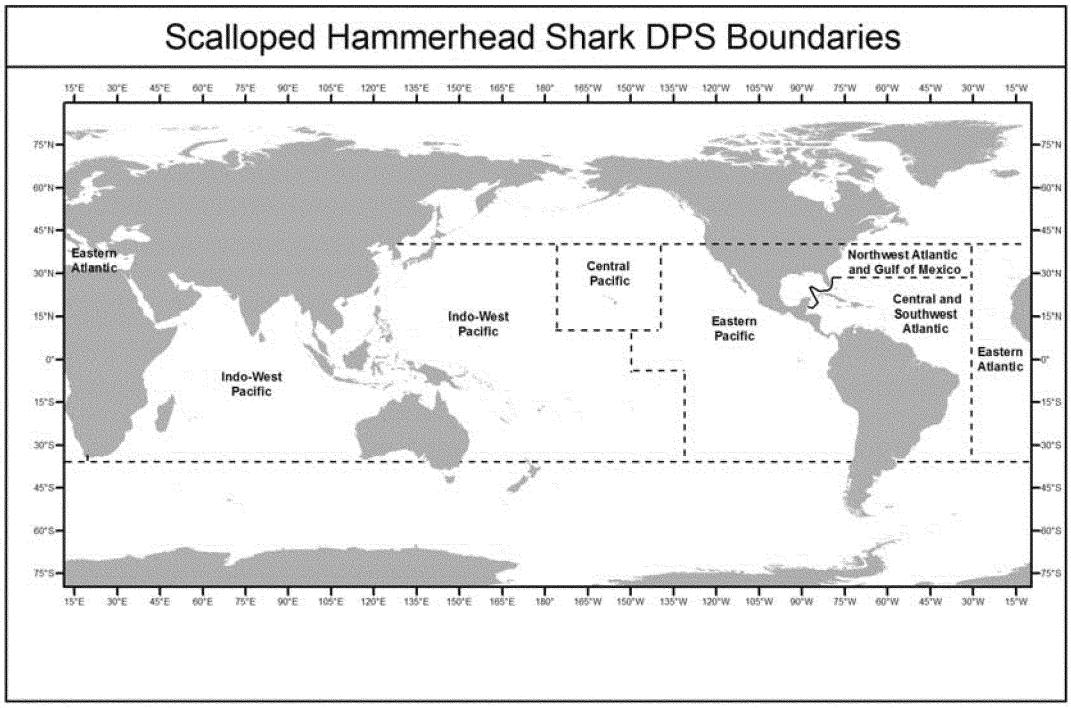

Figure 1. Map of the six scalloped hammerhead shark DPS boundaries.

Assessment of Extinction Risk

The Endangered Species Act (ESA) (Section 3) defines endangered species as ''any species which is in danger of extinction throughout all or a significant portion of its range.'' Threatened species are ''any species which is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range.'' Neither we nor the USFWS have developed any formal policy guidance about how to interpret the definitions of threatened and endangered. We consider a variety of information and apply professional judgment in evaluating the level of risk faced by a species in deciding whether the species is threatened or endangered. We evaluate both demographic risks, such as low abundance and productivity, and threats to the species including those related to the factors specified by the ESA Section 4(a)(1)(A)–(E).

Methods

As we have explained, we convened an ERA team to evaluate extinction risk to the species. This section discusses the methods used to evaluate threats to each DPS and draw overall extinction risk conclusions for each. As explained further down in this notice, we have separately taken into account other conservation efforts which have the potential to reduce threats identified by the ERA team.

For purposes of the risk assessment, an ERA team comprised of fishery biologists and shark experts was convened to review the best available information on the species and evaluate the overall risk of extinction facing the scalloped hammerhead shark now and in the foreseeable future. The term ''foreseeable future'' was defined as the timeframe over which threats could be reliably predicted to impact the biological status of the species. After considering the life history of the scalloped hammerhead shark, availability of data, and type of threats, the ERA team decided that the foreseeable future should be defined as approximately 3 generation times for the scalloped hammerhead shark, or 50 years. (A generation time is defined as the time it takes, on average, for a sexually mature female scalloped hammerhead shark to be replaced by offspring with the same spawning capacity). This timeframe (3 generation times) takes into account the time necessary to provide for the conservation and recovery of the species. As a late-maturing species, with slow growth rate and low productivity, it would likely take more than a generation time for any conservative management action to be realized and reflected in population abundance indices (as evidenced by the slow recovery of the NW Atlantic & GOM DPS discussed below).

In addition, the foreseeable future timeframe is also a function of the reliability of available data regarding the identified threats and extends only as far as the data allow for making reasonable predictions about the species' response to those threats. The ERA team considered extending foreseeable future out to 100 years as well, but after discussion, agreed that

they could not reliably predict the severity of threats, such as overutilization or inadequacy of regulatory measures, with any certainty past 50 years, given the changing nature of international and national fishery management and push towards conservation and control of illegal fishing. (As an aside, the timeframe of 3 generations is a widely used scientific indicator of biological status, and has been applied in decision making models by many other conservation management bodies, including the American Fisheries Society, the CITES, and the IUCN.)

Often the ability to measure or document risk factors is limited, and information is not quantitative or very often lacking altogether. Therefore, in assessing risk, it is important to include both qualitative and quantitative information. In previous NMFS status reviews, Biological Review Teams have used a risk matrix method to organize and summarize the professional judgment of a panel of knowledgeable scientists. This approach is described in detail by Wainright and Kope (1999) and has been used in Pacific salmonid status reviews as well as in the status reviews of many other species (see *http://www.nmfs.noaa.gov/pr/species/* for links to these reviews). In the risk matrix approach, the collective condition of individual populations is summarized at the DPS level according to four demographic risk criteria: Abundance, growth rate/productivity, spatial structure/connectivity, and diversity. These viability criteria, outlined in McElhany *et al.* (2000), reflect concepts that are well-founded in conservation biology and that individually and collectively provide strong indicators of extinction risk.

Using these concepts, the ERA team estimated the extinction risk of each scalloped hammerhead shark DPS based on current and future demographic risks by assigning a risk score to each of the four demographic criteria. The scoring for the risk criteria correspond to the following values: 1—no or very low risk, 2—low risk, 3—moderate risk, 4—high risk, and 5—very high risk. Likewise, the ERA team performed a threats assessment for each DPS by scoring the severity of current threats to the DPS as well as predicting whether the threat will increase, decrease, or stay the same in the foreseeable future. Detailed definitions of these risk scores can be found in the status review report. The scores were tallied (mode, median, range), reviewed by the ERA team, and considered in making the overall risk determination. Although this process helps to integrate and summarize a large amount of diverse information, there is no simple way to translate the risk matrix scores directly into a determination of overall extinction risk. Other descriptive statistics, such as mean, variance, and standard deviation, were not calculated as the ERA team felt these metrics would add artificial precision or accuracy to the results.

Guided by the results from the demographics risk analyses as well as the threats assessment, the ERA team members were asked to use their informed professional judgment to make an overall extinction risk determination for each DPS now and in the foreseeable future. For this analysis, the ERA team again defined five levels of extinction risk: 1—no or very low risk, 2—low risk, 3—moderate risk, 4—high risk, and 5—very high risk: however, the definitions differ slightly from those used in the demographic and threats assessment, and can be found in the status review report. To allow individuals to express uncertainty in determining the overall level of extinction risk facing the species, the ERA team adopted the ''likelihood point'' (FEMAT) method. This approach has been used in previous NMFS status reviews (e.g., Pacific salmon, Southern Resident killer whale, Puget Sound rockfish, Pacific herring, and black abalone) to structure the team's thinking and express levels of uncertainty when assigning risk categories. For this approach, each team member distributed 10 'likelihood points' among the five levels of risks. The scores were then tallied (mode, median, range) and summarized for each DPS.

Finally, the ERA team did not make recommendations as to whether the species should be listed as threatened or endangered. Rather, the ERA team drew scientific conclusions about the overall risk of extinction faced by each DPS under present conditions and in the foreseeable future based on an evaluation of the species' demographic risks and assessment of threats.

Demographic Data Reviewed by the ERA Team

The amount of available data on scalloped hammerhead shark abundance and trends varies by DPS. The abundance status of the NW Atlantic & GOM DPS is likely the best understood, with over 2 decades of data available from multiple recreational and commercial sources and analyzed in a recent stock assessment by Hayes *et al.* (2009). Recreational catch data used in this stock assessment were collected by the NMFS Marine Recreational Fishery Statistics Survey, NMFS' Southeast Region Headboat Survey, and the Texas Parks and Wildlife Department Marine Recreational Fishing Survey. These surveys have been in operation since the early 1970s and provide estimates of total catch data and CPUE data through random-dial telephone surveys, dockside intercept sampling programs, and self-reported logbook or daily catch record surveys. As these surveys do not provide data to estimate catch in biomass, the recreational survey data was only analyzed in terms of numbers of individual sharks. Commercial catch data used in the stock assessment were collected by the NMFS Southeast Fisheries Science Center from the Pelagic Dealer Compliance database and from the Accumulated Landings Systems. Landings weights were converted into catch numbers by dividing the weight by an average weight of the individual animal as reported in the Commercial Shark Fishery Observer Program. In this way, recreational and commercial catch numbers could be directly compared. Discard estimates specifically for scalloped hammerheads are not available before 1987 or after 2001 (due to *S. lewini* being lumped into a larger dealer report category), so estimates for these years were based on average discards in 1987–1992 and 1993–2001, respectively. Additionally, no catch was assumed to take place prior to 1981 based on insufficient catch data available before that year. This assumption was tested through sensitivity analyses and subsequently accepted by Hayes *et al.* (2009).

For the stock assessment, indices of relative abundance from fishery-dependent and -independent data were estimated for inclusion in surplus-production models to determine population projections and rebuilding probabilities. Fishery dependent indices were estimated through CPUE data provided by commercial fishery logbooks and observer programs and standardized according to the Lo method (Lo *et al.,* 1992). Fishery-independent surveys are less biased indices of abundance and were included in the models after standardization. Fishery-independent surveys are assumed to more accurately reflect population abundance due to their standardized sampling methods that are designed not to target specific concentrations of fish. The three fishery-independent surveys that were included in the stock assessment models are: the NMFS Pascagoula longline survey, which uses a standardized, random sampling design stratified by depth and covering the western Gulf of Mexico to North Carolina along the U.S.

southeastern Atlantic seaboard; the NMFS Panama city Gillnet Survey, which uses a standardized sampling design, with monofilament gillnets set at fixed stations monthly from April to October in shallow, coastal areas of the northwestern Gulf of Mexico close to the Florida panhandle; and the North Carolina longline survey, which uses a standardized sampling design, with unanchored longlines set biweekly off the central coast of North Carolina near Cape Lookout.

In addition to the stock assessment, the ERA team also considered other data sources of abundance estimates. This included a study by Ferretti *et al.* (2008), which provided historical records of shark catches from the Mediterranean Sea; however, the ERA team had concerns about the species-level identifications in the study. Some CPUE information, providing long-term trends data, was available from beach netting programs off the coasts of South Africa and Australia. The methods and materials from these beach protection programs have largely remained the same over the years, providing a good source of fishery-independent data. In South Africa, the beach protection programs have been in place since the early 1950s, providing catch rates of scalloped hammerhead sharks off various beaches from 1952 to 2003. In Australia, catch data from shark control programs off the coast of Queensland is available from 1986 to 2010. Other data sources for abundance analyses include: estimates of breeding individuals and pups from a scalloped hammerhead nursery ground in Hawaii, diver sighting reports from 1992–2004 in protected waters of the eastern Pacific, and estimates of the rate of population decline in the Gulf of Tehuantepac, Mexico.

Growth and productivity analyses were primarily based on data collected from scalloped hammerhead populations in the Atlantic Ocean as there is some scientific disagreement on the aging methodology used to interpret growth bands in studies on *S. lewini* from the Pacific Ocean. Scalloped hammerhead sharks develop opaque bands on their vertebrae, which are used to estimate age. For some studies conducted in the eastern and western Pacific, band formation was assumed to occur bi-annually, whereas in the Atlantic, bands were assumed to form annually (see Miller *et al.,* 2013). Although indirect age validation studies for *S. lewini* are still inconclusive, bomb radiocarbon and calcein methods (direct age validation methods) have been used to validate annual growth bands for two other species of *Sphyrna,* including the great hammerhead shark (*S. mokarran*) and the bonnethead shark (*S. tiburo*) (Parsons, 1993; Passerotti *et al.,* 2010). Therefore, it seems more likely that the scalloped hammerhead shark undergoes annual band formation, as has been found in other chondrichthyan growth studies (Campana *et al.,* 2002; Okamura and Semba, 2009), and this assumption was used when examining age maturity, growth, and productivity estimates.

For spatial structure/connectivity the ERA team considered the current and historical range of the taxon and the habitat requirements and physical characteristics of the habitat as documented in the scientific literature. With respect to diversity, the ERA team examined the genetic data, which provided estimates of migration rates per generation, and analyzed any potential threats of genetic bottlenecking or other ecological and human-caused factors that could substantially alter the rate of gene flow in the DPS.

Evaluation of Demographic Risks

NW Atlantic & GOM DPS

A recent assessment for the northwest Atlantic and Gulf of Mexico scalloped hammerhead shark stock concluded that the population has declined by over 80 percent since 1981 (Hayes *et al.,* 2009). Other studies have also reported similar decreases in *S. lewini* populations along the western Atlantic coast. For example, Baum *et al.* (2003) calculated that the northwest Atlantic population of *S. lewini* has declined 89 percent since 1986; however, this study is controversial due to its reliance on only pelagic longline logbook data. Off the southeastern U.S. coast, Beerkircher *et al.* (2002) observed significant declines in nominal CPUE for *S. lewini* between 1981–1983 (CPUE = 13.37; Berkeley and Campos, 1988) and 1992–2000 (CPUE = 0.48). On a smaller scale, Myers *et al.* (2007) documented a 98 percent decline of the *S. lewini* population off the coast of North Carolina between 1972 and 2003, using standardized CPUE data from shark targeted, fishery-independent surveys. However, the authors also discovered a significant increase in juvenile scalloped hammerheads (instantaneous rate of change = 0.094) from 1989 to 2005. Comparing estimates of population size off the coast of South Carolina, Ulrich (1996) reported a 66 percent decrease between 1983–1984 and 1991–1995. Although these declines in former abundance numbers are significant, the latest stock assessment for this DPS found that population numbers have remained fairly stable since 1995 (Hayes *et al.,* 2009). The stock assessment also predicted a 91 percent probability of the population rebuilding within 30 years under 2005 catch levels. From 2006 to 2010, the U.S. scalloped hammerhead harvest has been below this 2005 catch level. In addition, stronger management measures have been implemented in this fishery, with a scalloped hammerhead shark rebuilding plan expected in 2013, which we believe will substantially contribute to continued increases in abundance and stability of this DPS. As such, the ERA team concluded, and we agree, that the future levels of abundance of the NW Atlantic & GOM DPS alone are unlikely to contribute significantly to its risk of extinction.

The ERA team also noted that sharks, in general, have lower reproductive rates and growth rates compared to bony fishes. Estimates for the intrinsic rate of increase (r) for scalloped hammerhead sharks are relatively low, ranging from 0.028 to 0.121 (see Miller *et al.,* 2013), suggesting general vulnerability to depletion. But compared to other chondrichthyan species, scalloped hammerhead sharks actually show a moderate rebound potential to exploitation by pelagic longline fisheries common in this DPS (Cortés *et al.,* 2010; ICCAT, 2012).

In addition, the ERA team did not see habitat structure or connectivity as a potential risk to this DPS. Already, an extensive range of essential fish habitat (EFH) has been identified for both juveniles and adults of this DPS. EFH is the habitat necessary for spawning, breeding, feeding, and growth to maturity for a species, and NMFS, the regional fishery management councils, and other Federal agencies work together to minimize threats to these identified EFH areas. The current EFH for this DPS extends from the coastal areas in the Gulf of Mexico from Texas to the southern west coast of Florida and along the Atlantic U.S. southeast coast from Florida up to Long Island, NY. Scalloped hammerhead sharks of all developmental stages have been identified within this EFH range (NMFS, 2006), along the eastern Atlantic and Gulf of Mexico coast, which suggests that habitat connectivity does not appear to be a limiting factor in this DPS's survival. Habitat structure also does not appear to be a threat, with the sharks inhabiting a range of environments with varying complexity (from estuaries to open oceans). Because the shark resides in the water column, threats to changes in the physical characteristics of the water column, such as salinity, temperature, and dissolved oxygen, may pose the greatest

risk to this species. Estuaries and nearshore waters are especially susceptible to pollution from anthropogenic impacts and subsequent water quality degradation. However, the species is highly mobile with no data to suggest it is restricted to any specific estuarine or shallow coastal area for use as a habitat ground. In addition, the degree to which habitat alterations have affected this shark species is not currently known (NMFS, 2009). As such, the ERA team concluded, and we agree, that habitat structure or connectivity is not a present risk to this DPS.

Central & SW Atlantic DPS

The ERA team noted that specific abundance numbers for this DPS are unavailable but likely similar to, and probably worse than, those found in the NW Atlantic & GOM DPS, mainly due to the observed intensive fishing pressure on this DPS. In the late 1990s, Amorim *et al.* (1998) remarked that heavy fishing by longliners led to a decrease in this population off the coast of Brazil. According to the FAO global capture production database, Brazil reported a significant increase in catch of *S. lewini* during this period, from 30 mt in 1999 to 508 mt by 2002, before decreasing to a low of 87 mt in 2009. Documented heavy inshore fishing has also led to significant declines of adult female *S. lewini* abundance (up to 90 percent) (CITES, 2010) as well as targeted fishing of and reported decreases in juvenile and neonate scalloped hammerhead populations (Vooren *et al.,* 2005; Kotas *et al.,* 2008). Information from surface longline and bottom gillnet fisheries targeting hammerhead sharks off southern Brazil indicates declines of more than 80 percent in CPUE from 2000 to 2008, with the targeted hammerhead fishery abandoned after 2008 due to the rarity of the species (FAO, 2010). The population abundance in the Caribbean is unknown as catch reporting is sporadic and not normally recorded down to the species level.

However, unlike the NW Atlantic & GOM DPS, exploitation of this DPS continues to go largely unregulated. In Central America, a lack of resources has led to poor enforcement of fishery regulations as well as frequent incidences of illegal fishing (further discussed in the Inadequacy of Existing Regulatory Mechanisms section). In Brazilian waters, there are very few fishery regulations that help protect hammerhead populations. For example, the minimum legal size for a scalloped hammerhead caught in Brazilian waters is 60 cm total length; however, *S. lewini* pups may range from 38 cm to 55 cm. As the pup sizes are very close to this minimum limit, the legislation is essentially ineffective, and as such, large catches of both juveniles and neonates have been documented from this region (Silveira *et al.,* 2007; Kotas *et al.,* 2008; CITES, 2010). Although Brazil has implemented other measures aimed at protecting species that use inshore areas as nursery grounds, such as by limiting gillnets and closing off certain fishing areas, unlike the management measures in the NW Atlantic & GOM DPS, these regulations are poorly enforced. Because of the lack of enforced fishery regulations, fishers continue to take large numbers of all ages of scalloped hammerhead sharks from inshore and coastal waters of this DPS. These threats, which have contributed to the decline in abundance of this DPS, and will continue to do so into the foreseeable future, are discussed in more detail below. Given the scalloped hammerhead shark's low intrinsic productivity, the observed downward trends in reported catches and population numbers, and continued threat from bycatch and directed catch in weakly regulated commercial and recreational fisheries, the ERA team concluded, and we agree, that the DPS' current and future levels of abundance are likely to contribute significantly to its risk of extinction.

Eastern Atlantic DPS

Abundance numbers for this DPS are unavailable or unreliable, but population trends likely reflect those found in the NW Atlantic & GOM DPS based on the similar fishing effort of longline fleets in this area (Zeeberg *et al.* 2006; CITES, 2010). One study that the ERA team reviewed used historical records to estimate declines of > 99.99 percent in both biomass and abundance of scalloped hammerhead sharks over the past 100 years in the Mediterranean Sea (Ferretti *et al.,* 2008). However, the ERA team voiced concerns regarding the species identification in the records, as many of the hammerheads found in the Mediterranean Sea are actually the similarly-looking smooth, not scalloped, hammerhead shark. Recently, Sperone *et al.* (2012) confirmed the presence of both *S. lewini* and *S. zyganea* around southern Italy, providing evidence that the species can still be found in the Mediterranean Sea.

According to data provided to the FAO, *S. lewini* abundance off the coast of Mauritania has declined by 95 percent since 1999, with evidence of a decrease in average size of the shark since 2006 (FAO, 2013). Abundance trends from off the coast of other western African countries are not available but likely similar to the situation off Mauritania (FAO, 2013). The status of other stocks from this region may also provide a likely picture of the scalloped hammerhead shark population in this region. According to the latest FAO report on the State of World Fisheries and Aquaculture, most of the pelagic stocks and demersal fish from the Eastern Central Atlantic are considered fully exploited to overexploited (FAO, 2012). In addition, many of the shrimp stocks range between fully and overexploited and the commercially important octopus and cuttlefish stocks in this region are deemed overexploited. Some stocks, such as the white grouper in Senegal and Mauritania, are even considered to be in severe condition. Driving this exploitation is the increasing need for protein resources in this region, both as a trade commodity and as a dietary staple. In fact, many people in Sub-Saharan Africa depend on fish for protein in their diet, with fish accounting for around 22 percent of their protein intake (Heck and Béné, 2005). This proportion increases to over 50 percent in many of the poorer African countries, where other animal protein is scarce, and in West African coastal countries, where fishing has driven the economy for many centuries (Heck and Béné, 2005). For example, fish accounts for 47 percent of protein intake in Senegal, 62 percent in Gambia, and 63 percent in Sierra Leone and Ghana (Heck and Béné, 2005). With this reliance on fish stocks for dietary protein as well as a sole source of income for many people in this region, it is not surprising that the FAO reports that ''the Eastern Central Atlantic has 43 percent of its assessed stocks fully exploited, 53 percent overexploited and 4 percent non-fully exploited, a situation warranting attention for improvement in management.'' (FAO, 2012)

With evidence to suggest that large artisanal fisheries are taking substantial amounts of juvenile scalloped hammerhead sharks from these waters, and reports of fisheries even specializing in catching sphyrnid species (CITES, 2010), it is highly likely that this DPS' status is similar to the status of other fish stocks in this region (i.e., fully to overexploited). Thus, taking into consideration the species' low intrinsic rate of productivity, the largely unregulated catch of the species off West Africa with indications of abundance declines and possible size truncation, threats from overexploitation and poor management,

and the rising demand for food/protein in this region (projected to double by 2020; World Bank, 2012), the ERA team concluded, and we agree, that future abundance levels of this DPS are likely to contribute significantly to its risk of extinction. These threats, which have contributed to the decline in abundance of this DPS, and will continue to do so into the foreseeable future, are discussed in more detail below.

Indo-West Pacific DPS

Beach protection programs in the Indo-West Pacific region have provided valuable fishery-independent data that reveal drastic declines in this scalloped hammerhead shark population since the early 1950s. Specifically, declines of 99 percent, 86 percent, and 64 percent have been estimated for *S. lewini* from catch rates in shark nets deployed off the beaches of South Africa from 1952–1972, 1961–1972, and 1978–2003, respectively (Dudley and Simpfendorfer, 2006; Ferretti *et al.,* 2010). Estimates of the decline in Australian hammerhead abundance range from 58–85 percent (Heupel and McAuley 2007; CITES, 2010). CPUE data from the northern Australian shark fishery indicate declines of 58–76 percent in hammerhead abundance in Australia's northwest marine region from 1996–2005 (Heupel and McAuley, 2007). Data from protective shark meshing programs off beaches in New South Wales (NSW) and Queensland also suggest significant declines in hammerhead populations off the east coast of Australia. From 1973 to 2008, the number of hammerheads caught per year in NSW beach nets decreased by more than 90 percent, from over 300 individuals to fewer than 30 (Reid and Krogh, 1992; Williamson, 2011). Similarly, data from the Queensland shark control program indicate declines of around 79 percent in hammerhead shark abundance between the years of 1986 and 2010, with *S. lewini* abundance fluctuating over the years but showing a recent decline of 63 percent between 2005 and 2010 (QLD DEEDI, 2011). Although these studies provide evidence of declining local populations, there is a high degree of uncertainty regarding the overall population size given the expansive range of this DPS.

Additionally, the ERA team noted that the coastal habitats of this DPS, especially around the island nations of the western Pacific, are less connected than those of the other DPSs that have a contiguous coastline. But since the western Pacific islands are relatively close together or connected by various submarine features, the ERA team felt that these areas are easily accessible to this DPS and therefore should pose minimal ecological risk. Overall, the ERA team recognized that the total abundance for this species in the entire region is not well known, but the available data confirm localized depletions of populations. This information, coupled with the species' low intrinsic rate of productivity, led the ERA team to conclude that the abundance in the foreseeable future may decline to a level that would not provide the DPS adequate resilience to environmental or anthropogenic perturbations. We agree with the ERA team's findings.

Central Pacific DPS

Abundance in this DPS is perceived to be high based on shark pup data from this region as well as personal observations from NMFS fishery scientists in the Pacific Islands Fishery Science Center. In Kāneʻohe Bay, a large nursery ground in Oahu, Hawaii, estimates of 7700 ± 2240 SD scalloped hammerhead sharks are born per year, which suggests that between 180 and 660 adult female sharks use this area annually as a birthing ground (Duncan and Holland, 2006). Growth rate of these pups is estimated to be 9.6 cm per year (Duncan and Holland, 2006). Although Clarke (1971) observed high predation on the pups by adult scalloped hammerheads, the author noted that the pup population remained high and suggested that either the pup population is significantly larger than previously thought, or that new births are compensating for the mortality of the pups in this nursery ground.

With respect to spatial structure and connectivity, this DPS has a high degree of isolation. However, while the population is limited in its connection to other coastal habitat areas, the fragmented habitats that are within this DPS are traversable, connected by various submarine features like seamounts and guyots. In addition, a number of suitable nursery grounds have been identified within this DPS. Thus, although the isolation of the DPS in the middle of the Pacific Ocean may pose a moderate risk to the species, the ERA team concluded, and we agree, that high abundance numbers and ample suitable nursery habitats protect the scalloped hammerhead shark population from extinction, with current levels of abundance unlikely to contribute significantly to this DPS' risk of extinction now or in the foreseeable future.

Eastern Pacific DPS

The ERA team commented that there are few good abundance data from this region; however, reports of substantial legal and illegal takes of *S. lewini,* and observed declines in scalloped hammerhead abundance and overall shark abundance, including in protected waters, suggest significant reductions in abundance of this species. Scalloped hammerhead sharks of all age classes are caught in substantial numbers by fisheries operating in this region (Perez-Jimenez *et al.,* 2005; Román-Vedesoto and Orozco-Zöller 2005; INP, 2006; Bizarro *et al.,* 2009; Arriatti, 2011). Some artisanal fisheries primarily target juvenile *S. lewini* (Arriatti, 2011), while other fisheries, like the tuna purse seine fisheries, catch significant numbers of the sharks as bycatch (Román-Vedesoto and Orozco-Zöller, 2005). In the Gulf of Tehuantepac, in Pacific southeastern Mexico, it is estimated that the scalloped hammerhead population is currently decreasing by 6 percent per year (INP, 2006). From 1996–2001, CPUE of all sharks in the Gulf of Tehuantepac declined by around 46 percent, and for *S. lewini,* CPUE declined to nearly zero in 2001 (INP, 2006). Farther south, in the Costa Rica EEZ, analysis of survey research and catch data from 1991–1992 and 1999–2000 indicate a decline of 58 percent in relative pelagic shark abundance (Arauz *et al.,* 2004). In Costa Rica's Pacific mahi-mahi targeted longline fishery, the mean CPUE (per 1,000 hooks) of *S. lewini* between 1999 and 2008 was low (0.041 ± 0.279); however, the majority of the fishing effort was concentrated in pelagic waters (from 19.5 to 596.2 km offshore) (Whoriskey *et al.,* 2011). More troubling are the diver reports of *S. lewini* populations in the protected waters around Cocos Island National Park. Analysis of these reports indicate declines of 71 percent in this protected *S. lewini* population, and suggest substantial fishing on this population by illegal, unreported, and unregulated (IUU) fishing vessels (Myers *et al.,* n.d.). Furthermore, landings data from the Pacific Mexican coast suggest a possible size truncation of this *S. lewini* population, with larger animals less common in 2007–2009 landings compared to those from 1998–1999 (Bizarro *et al.,* 2009). The removal of larger, and hence, likely mature animals can decrease the productivity of the population, particularly for slow-growing, long-lived species such as the scalloped hammerhead shark. From an evolutionary standpoint, Nance *et al.* (2011) calculated that this DPS has undergone significant declines (1–3

orders of magnitude) from its ancestral population, with the onset of decline occurring approximately 3600 to 12,000 years ago. Thus, given the observed decreases in population and possible size truncation, low intrinsic productivity of the species, and evidence of significant legal and illegal fishing of this DPS, suggesting a need for better fisheries management or enforcement, the ERA team concluded, and we agree, that the current abundance may be at a level that contributes significantly to the DPS' risk of extinction now and in the foreseeable future. These threats (significant legal and illegal fishing), which have contributed to the decline in abundance of this DPS, and will continue to do so into the foreseeable future, are discussed in more detail below.

Summary of Factors Affecting the Six DPSs of Scalloped Hammerhead Sharks

As described above, section 4(a)(1) of the ESA and NMFS implementing regulations (50 CFR 424) state that we must determine whether a species is endangered or threatened because of any one or a combination of the following factors: (1) The present or threatened destruction, modification, or curtailment of its habitat or range; (2) overutilization for commercial, recreational, scientific, or educational purposes; (3) disease or predation; (4) inadequacy of existing regulatory mechanisms; or (5) other natural or man-made factors affecting its continued existence. The ERA team evaluated whether and the extent to which each of the foregoing factors contributed to the overall extinction risk of the six DPSs. The status report identifies the most serious individual threat(s) to a DPS' persistence. It also identifies those threats that, in combination with others, were thought to contribute significantly to the risk of a DPS' extinction. This section briefly summarizes the ERA team's findings and our conclusions regarding threats to scalloped hammerhead sharks with occasional focus on threats specific to individual DPSs. More details can be found in the status review report (Miller *et al.,* 2013).

The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range

The ERA team identified habitat destruction as a potential threat to the scalloped hammerhead shark, but did not find evidence to suggest that it is presently contributing significantly to any of the DPS's risks of extinction. Currently, scalloped hammerhead sharks are found worldwide, residing in coastal warm temperate and tropical seas and rarely in waters cooler than 22 °C (Compagno, 1984; Schulze-Haugen and Kohler, 2003). They occur over continental and insular shelves and adjacent deep waters, but can also be found in intertidal and surface waters and depths of up to 450 to 512 m (Sanches, 1991; Klimley, 1993). Estuaries and coastal embayments have been identified as particularly important nursery areas for scalloped hammerhead sharks range wide, while offshore waters contain important spawning and feeding areas. The vertical habitat of scalloped hammerheads in the Gulf of California may extend even farther to include areas of cold hypoxic waters (Jorgensen *et al.,* 2009), indicating an ability to tolerate large fluctuations in temperature and dissolved oxygen concentrations.

In the U.S. EEZ, the MSA requires NMFS to identify and describe EFH in FMPs, minimize the adverse effects of fishing on EFH, and identify actions to encourage the conservation and enhancement of EFH. Towards that end, NMFS has funded two cooperative survey programs intended to help delineate shark nursery habitats in the Atlantic and Gulf of Mexico. The Cooperative Atlantic States Shark Pupping and Nursery Survey and the Cooperative Gulf of Mexico States Shark Pupping and Nursery Survey are designed to assess the geographical and seasonal extent of shark nursery habitat, determine which shark species use these areas, and gauge the relative importance of these coastal habitats for use in EFH determinations. Results from the surveys indicate the importance of estuarine, nearshore, and coastal waters of South Carolina, Georgia, Atlantic Florida, Florida Panhandle, and Alabama as potential nursery habitats for scalloped hammerhead sharks along the eastern U.S. Coast and Gulf of Mexico. Since the scalloped hammerhead EFH is defined as the water column or attributes of the water column, NMFS determined that there are minimal or no cumulative anticipated impacts to the EFH from gear used in HMS and non-HMS fisheries, basing its finding on an examination of published literature and anecdotal evidence (NMFS, 2006).

Likewise, scalloped hammerhead shark habitat in the other DPSs is similar to what is found in the NW Atlantic & GOM DPS, characterized primarily by the water column attributes. For example, Zeeberg *et al.* (2006) noted an increase in abundance of hammerhead bycatch in pelagic trawlers operating in the Mauritania EEZ during the summer months, which suggested frequent use of these waters as habitat areas by scalloped hammerheads. However, bycatch probability decreased significantly during the winter and spring, as trade wind-induced upwellings caused sea surface temperatures to drop from summer maximums of 30 °C to 18 °C, indicating sea surface temperature as a significant habitat determinant. Likewise, Bessudo *et al.* (2011) found that the depth at which scalloped hammerhead sharks commonly swam around Malpelo Island in the Eastern Pacific coincided with the thermocline, the temperature-based transition layer between the mixed layer at the surface and the deep water layer. The authors also suggested that scalloped hammerhead seasonal movements to and from the island of Malpelo are linked to oceanographic conditions, with seasonal environmental signals triggering the migratory movements (Bessudo *et al.,* 2011).

To date, no studies have looked at habitat alteration effects on scalloped hammerhead shark populations. However, any modifications would most likely affect *S. lewini* nursery habitats as these waters are usually shallower, located closer inshore, and thus are more susceptible to anthropogenic inputs than the offshore habitats. Examples of identified scalloped hammerhead pupping grounds include the Tárcoles River in the Gulf of Nicoya, Guam's Apra Harbor, Kāneʻohe Bay in Oahu, Hawaii, and coastal waters off Oaxaca, Mexico and the Republic of Transkei. These waters are or may be used by humans for a variety of purposes that often result in degradation of these and adjacent habitats, posing threats, either directly or indirectly, to the biota they support (NMFS, 2006). These effects, either alone or in combination with effects from other activities within the ecosystem, may contribute to the decline of the species or degradation of the habitat. The ERA team specifically noted that the increased industrialization seen within the scalloped hammerhead shark range could result in loss of coastal and nearshore habitats and higher pollutants in waters used by the scalloped hammerhead shark. For example, in Costa Rica, the increased industrialization and subsequent waste from commercial, industrial, and transportation activities, as well as coffee production and cattle farming, has led to the accumulation of heavy metals near the mouth of a river frequently used as a scalloped hammerhead shark nursery ground (Zanella *et al.,* 2009). High

concentrations of heavy metals damage the epithelial gill cells of sharks and cause respiratory system failure (de Boeck *et al.,* 2002); however, such effects to *S. lewini* have not yet been reported in this area or elsewhere in the species' range. Although severe pollution and the degradation of water quality may be serious threats to *S. lewini* nursery and juvenile habitats range wide, the ERA team also noted that this species usually prefers more turbid and murkier waters. Data from Kāneʻohe Bay in Hawaii show that juvenile scalloped hammerheads prefer to aggregate in deeper water during the day, where the habitat is composed mainly of mud and silt (Duncan and Holland, 2006). Areas of higher hammerhead shark abundance also corresponded to locations of greater turbidity and higher sedimentation and nutrient flow (Duncan and Holland, 2006). This was also true of scalloped hammerheads in the Eastern Pacific, with large adult schools gathering on the sides of islands where the current was strongest, and juvenile scalloped hammerheads frequenting shallow, turbid waters at the mouth of rivers (Garro *et al.,* 2009; Zanella *et al.,* 2009). As such, characteristics usually associated with coastal habitat degradation (such as runoff, siltation, eutrophication, etc.) could actually enhance some of the habitat for this species to a degree, creating more sediment and nutrient rich waters.

Because the scalloped hammerhead range is mainly comprised of open ocean environments occurring over broad geographic ranges, large-scale impacts such as global climate change that affect ocean temperatures, currents, and potentially food chain dynamics, are most likely to pose the greatest threat to this species. Additionally, the scalloped hammerhead shark is highly mobile within the range of its DPS, and there is no evidence to suggest its access to essential habitat is restricted within any of the DPSs. It also does not participate in natal homing, which would essentially restrict the species to a specific nursery ground, but rather has been found utilizing artificially enlarged estuaries as nursery habitats located 100 to 600 km from established nursery grounds (Duncan *et al.,* 2006). Also, based on a comparison of *S. lewini* distribution maps from 1984 (Compagno, 1984) and 2012 (Bester, n.d.), and current reports of scalloped hammerhead catches in FAO fishing areas, there is no evidence to suggest a range contraction for any DPS based on habitat degradation. Overall, using the best available information, there is no evidence to suggest there exists a present or threatened destruction, modification, or curtailment of the scalloped hammerhead shark's habitat or range and we conclude that it is unlikely that this factor is contributing on its own or in combination with other factors to the extinction risk of any of the six DPSs evaluated.

Overutilization for Commercial, Recreational, Scientific or Educational Purposes

The ERA team identified overutilization for commercial and/or recreational purposes as a moderate to major threat contributing to extinction risk for all six scalloped hammerhead shark DPSs. Scalloped hammerhead sharks are targeted by industrial, commercial, artisanal and recreational fisheries, and caught as bycatch in many other fisheries, including pelagic longline tuna and swordfish fisheries and purse seine fisheries. Unfortunately, significant catches of scalloped hammerheads have and continue to go unrecorded in many countries. In addition, scalloped hammerheads are likely under-reported in catch records, as many records do not account for discards (example: Where the fins are kept but the carcass is discarded) or reflect dressed weights instead of live weights. Also, many catch records do not differentiate between the hammerhead species, or shark species in general, and thus species-specific population trends for scalloped hammerheads are not readily available. Thus, the lack of catch data on scalloped hammerhead sharks makes it impossible to estimate rates of fishing mortality for many of the DPSs, or conduct detailed quantitative analyses of the effects of fishing on the scalloped hammerhead populations. Nonetheless, there is little doubt that overfishing has played a major role in the decline of scalloped hammerhead sharks, and many other shark species for that matter, around the world (Lack and Sant, 2011).

Estimates of worldwide catches of sphyrnids are reported in the FAO Global Capture Production dataset mainly at the family level, but a select number of countries have reported down to the species level. Total catches of the hammerhead family have increased since the early 1990s (prior years were not reported), from 377 mt in 1991 to a current peak of 5,786 mt in 2010. This rise is in contrast to the catches of *S. lewini,* which have decreased, for the most part, since reaching a maximum of 798 mt in 2002, suggesting a possible decline in population abundance. However, only seven countries have reported *S. lewini* data in this FAO database, which is by no means an accurate representation of worldwide *S. lewini* landings data. Additionally, these FAO data do not include discard mortalities. In order to gain a better estimate of the global shark catch, the ERA team reviewed a study by Clarke *et al.* (2006a, 2006b), which analyzed 1999–2001 Hong Kong fin trade auction data in conjunction with species-specific fin weights and genetic information. Scalloped hammerhead sharks are popular in the international fin trade due to their large fins with a high fin needle content (a gelatinous product used to make shark fin soup), and subsequently fetch a high commercial price (Abercrombie *et al.,* 2005). These fins are found under the second most traded fin category in the Hong Kong market. Applying a Bayesian statistical method to the trade auction data, it was estimated that between 1 and 3 million smooth and scalloped hammerhead sharks, with an equivalent biomass of 60–70 thousand mt, are traded annually (Clarke *et al.,* 2006b). These estimates are significantly higher than the catches reported to FAO, and suggest that FAO catch data should only be used as coarse estimates. To put these numbers into perspective, Hayes *et al.* (2009) estimated the virgin, or unfished, population size (in 1981) of the Northwest Atlantic and Gulf of Mexico scalloped hammerhead stock to be in the range of 142,000—169,000 individuals.

Given the high exploitation rates and vulnerability of the scalloped hammerhead shark to overfishing, the ERA team identified overutilization, especially for the international fin trade, as the most severe threat to the global scalloped hammerhead shark population. With respect to each DPS, the severity of this threat to its risk of extinction is briefly explained below.

NW Atlantic & GOM DPS

The ERA team identified the threat of overutilization by commercial and recreational fisheries as a moderate risk to the extinction of the NW Atlantic & GOM DPS of scalloped hammerhead sharks, but projected the threat to decrease in the foreseeable future. In the Atlantic U.S., scalloped hammerhead sharks are considered a highly migratory species (HMS), with this DPS managed as part of the U.S. Atlantic HMS fisheries. These scalloped hammerhead sharks are mainly caught by directed shark permit holders using bottom longline gear. To a lesser degree they are caught as bycatch in longline and coastal gillnet fisheries. In the recreational fisheries sector, scalloped

hammerheads became a popular target species of fishers in the last several decades following the release of the movie ''Jaws'' (Hayes *et al.,* 2009). Data from multiple sources indicate that the NW Atlantic & GOM DPS has experienced severe declines over the past few decades. It is likely that these scalloped hammerhead sharks were overfished beginning in the early 1980s and experienced periodic overfishing from 1983 to 2005 (Jiao *et al.,* 2011).

In October 2009, Hayes *et al.* (2009) produced a stock assessment for the U.S. Northwest Atlantic and Gulf of Mexico population of scalloped hammerhead sharks, which NMFS reviewed and deemed appropriate for the basis of U.S. management decisions. The stock assessment incorporated both recreational and commercial catch information as well as discard estimates since 1981, and developed abundance indices from fishery-dependent and –independent surveys. From 1981–1990, a total of 181,544 scalloped hammerhead sharks from the NW Atlantic & GOM DPS were estimated as caught, primarily by recreational fishers. In fact, the recreational fishery sector accounted for over 90 percent of this harvest. However, as the demand for shark products grew (including meat, cartilage, and the highly prized fins), so did the commercial shark fishery in the Atlantic, which saw expansion throughout the late 1970s and the 1980s (NMFS, 2006). Specifically, tuna and swordfish vessels started to retain a greater proportion of their shark incidental catch, and some directed fishery effort expanded as well. Subsequently, catches accelerated through the 1980s and shark stocks, especially the scalloped hammerhead shark, began to show signs of decline (NMFS, 2006). After 1993, the estimated harvest of scalloped hammerhead sharks decreased dramatically from 22,330 to 4,554 individuals; however, it should be noted that it was at this time when NMFS implemented an FMP for Sharks of the Atlantic Ocean. Due to the concern over the possibility of the Atlantic shark resource being overfished, the 1993 Shark FMP established quotas, monitoring measures, and a rebuilding plan for the large coastal shark fishery (NMFS, 1993). In the following years, NMFS continued to revise these quotas based on the latest stock assessment data, and developed stronger management measures for the fishery, which likely explains the decrease in catch of scalloped hammerhead sharks. Since 1993, the harvest of scalloped hammerhead sharks has remained below 7,800 individuals, with the average annual harvest of this DPS from 1995–2005 only about a quarter of the pre-1990 levels (Hayes *et al.,* 2009).

Using two forms of a surplus-production model, a logistic (Schaefer, 1954) and Fox (1970) model, Hayes *et al.* (2009) calculated annual fishing mortality (F), maximum sustainable yield (MSY), and the size (N) of both the unfished and fished scalloped hammerhead shark population in the U.S. Northwest Atlantic and Gulf of Mexico. Both models showed that overfishing is likely occurring ($F > F_{MSY}$) with a greater than 95 percent probability that the population is overfished ($N < N_{MSY}$). The logistic model estimated a population size in 2005 to be 35 percent (CI = 19–87 percent) of the population at MSY, with an estimated F of 114 percent (CI = 43–397 percent) of F_{MSY}, whereas the Fox model estimated the population size to be 45 percent (CI = 18–89 percent) of N_{MSY} and F to be 129 percent (CI = 54–341 percent) of F_{MSY}. Both models estimated a depletion of around 83 percent from the virgin population size (in 1981). However, under a constant catch at the 2005 harvest level, the probability that the stock of scalloped hammerheads will rebuild within 30 years was estimated to be 91 percent (with rebuilding defined as reaching a population size greater than N_{MSY}).

Since 2005, the catches of this DPS have remained fairly low in all U.S. fishery sectors. In the Atlantic HMS fishery, an average of 25 vessels landed 181 hammerhead sharks per year from 2005 to 2009 on pelagic longline gear (based on logbook data). In bottom longline (BLL) hauls, observed catches of scalloped hammerhead sharks have varied by year. In 2007, 39 individuals were observed in the BLL catch. This number increased to 539 individuals in 2009, and then dropped 1 year later to 328, with *S. lewini* comprising ≤ 2.8 percent of the total number of sharks caught in the BLL hauls. However, comparisons of these catches should be made with caution, as the number of participating vessels, hauls, and trips vary greatly by year. In the gillnet fishery, the scalloped hammerhead shark is no longer a frequently caught bycatch species. In 2010, 4 drift gillnet vessels were observed making 14 sets on 8 trips. Out of the total 2,728 sharks caught during these trips, scalloped hammerhead sharks comprised only 1.2 percent (n = 33). In the sink gillnet fishery, 17 vessels were observed making 281 sets on 53 trips in 2010. A total of 3,131 sharks were caught, with scalloped hammerhead sharks comprising only 0.6 percent of this total (n = 19) (Passerotti *et al.,* 2011). Recreational harvest of scalloped hammerhead sharks has also seen a decrease from the 1980s and early 1990 numbers, likely due to the establishment of bag limits beginning in 1993, and regulations limiting this fishery to only rod and reel and handline gear in 2003.

The ERA team ranked the threat of overutilization as a moderate risk, one that would contribute significantly to risk of extinction only in combination with other factors, such as low and decreasing abundance or inadequate regulatory mechanisms. However, given the increase in management of the fishery since the early 1990s, the subsequent infrequent occurrence of the species in fishing gear, the stable abundance numbers, and the fact that both the U.S. commercial and recreational harvest of this DPS have been below the recommended rebuilding catch levels since 2005 (which will allow abundance levels to increase in the foreseeable future), the ERA team concluded, and we agree, that the available data suggest that the current threat of overutilization by commercial and recreational fisheries has been greatly reduced, minimized by the effectiveness of the existing fishery management measures, and by itself will not contribute significantly to this DPS' risk of extinction in the foreseeable future.

Central & SW Atlantic DPS

The ERA team identified the threat of overutilization by industrial/commercial fisheries as a high risk and overutilization by artisanal fisheries as a moderate risk to the extinction of the Central & SW Atlantic DPS, with the threat projected to increase in the foreseeable future. Brazil, the country that reports one of the highest scalloped hammerhead landings in South America, maintains heavy industrial fishing of this species off its coastal waters. In the ports of Rio Grande and Itajai, annual landings of hammerhead sharks have fluctuated over the years, but have reached significantly high numbers. For example, in 1992, reported landings were approximately 30 mt but increased rapidly to 700 mt in 1994. From 1995 to 2002, catches decreased but fluctuated between 100–300 mt (Baum *et al.,* 2007). FAO global capture production statistics from Brazil show a significant increase in catch of *S. lewini,* from 30 mt in 1999 to 262 mt in 2000. In 2001 and 2002, catches almost doubled to 507 mt and 508 mt, respectively, before decreasing to 87 mt in 2009.

High numbers of hammerhead sharks have also been removed by longliners fishing off the coast of South America. Data from a tuna fishery based in Santos City, São Paulo State, Brazil, revealed that although longliners mainly target tuna, sharks have become popular as incidental take (Amroim *et al.,* 1998). In fact, from 1983–1994 Santos longliners began targeting sharks at least part of the time during their trips, and by 1993, sharks comprised approximately 60 percent of the total longline catch. The total hammerhead yield (includes *S. lewini* and *S. zyganea*) increased slightly from 1972 (7 mt) to 1988 (79 mt), and then more significantly to a maximum of 290 mt in 1990 (as did the number of longliners catching sharks). During the study period (from 1974–1997), *S. lewini* catch was reported throughout the year and represented approximately 60 percent of the total hammerhead yield. After 1990, hammerhead yield exhibited a decreasing trend (to 59 mt in 1996), but this may have been a result of a change in gear from traditional Japanese longline to monofilament longline (Amorim *et al.,* 1998). However, despite this change in gear, a follow-up study conducted from 2007–2008 found that São Paulo State longliners were still targeting sharks, and that the catch was dominated by shark species (catch composition: Sharks = 49.2 percent, swordfish = 35.5 percent, billfish, tuna, other = 15.3 percent) (Amorim *et al.,* 2011). By weight, hammerheads represented only 6.3 percent of the total shark catch, or 37.7 mt, a decrease from the previously reported yield in 1996. Of the 376 hammerhead sharks caught, 131 (or 35 percent) were *S. lewini* (Amorim *et al.,* 2011).

S. lewini is also commonly landed by artisanal fishers in the Central and Southwest Atlantic, with concentrated fishing effort in nearshore and inshore waters, areas likely to be used as nursery grounds. In the Caribbean, specific catch and landings data are unavailable; however, *S. lewini* is often a target of artisanal fisheries off Trinidad and Tobago and Guyana, and anecdotal reports of declines in abundance, size, and distribution shifts of sharks suggest significant fishing pressure on overall shark populations in this region (Kyne *et al.,* 2012). Additionally, Chapman *et al.* (2009) recently linked *S. lewini* fins from Hong Kong fin traders to the Central American Caribbean region, suggesting the lucrative fin trade may partially be driving the artisanal and commercial fishing of this DPS. Farther south, in Brazil, artisanal fisheries make up about 50 percent of the fishing sector, with many fishers focusing their efforts inshore on schools of hammerheads. Between 1993 and 2001, adult female *S. lewini* abundance in Brazil decreased by 60–90 percent due to this inshore fishing pressure (CITES, 2010). In 2004, Brazil recognized this threat of *S. lewini* overutilization in its waters and subsequently added the species to its list of over-exploited species (Normative Instruction MMA n° 05); however, this listing does not carry with it any prohibitions on fishing for the species. Thus, given the available data on catch trends, yields, fishing effort, and fin trade incentives, the ERA team concluded, and we agree, that the threat of overutilization alone is likely to contribute significantly to risk of extinction for the Central & SW Atlantic DPS.

Eastern Atlantic DPS

The ERA team identified the threat of overutilization by industrial/commercial fisheries as a high risk to the extinction of the Eastern Atlantic DPS, with the threat projected to increase in the foreseeable future. Although species-specific data are unavailable from this region, hammerheads are a large component of the bycatch in the European pelagic freezer-trawler fishery that operates off Mauritania. Between 2001 and 2005, 42 percent of the retained pelagic megafauna bycatch from over 1,400 freezer-trawl sets consisted of hammerhead species (*S. lewini, S. zygaena,* and *S. mokarran*) (Zeeberg *et al.,* 2006). Of concern, especially as it relates to abundance and recruitment to the population, is the fact that around 75 percent of the hammerhead catch were juveniles of 0.50–1.40 m in length (Zeeberg *et al.,* 2006).

In 2009, the European Union (EU) ranked second in the world for landings of sharks, rays, and chimaeras (according to FAO catch statistics), with landings estimated at 112,329 mt. The total amount of hammerhead sharks landed was 227 mt, with Spanish vessels responsible for 78 percent of the catch (178 mt), followed by Portugal (37 mt) (Shark Alliance, 2012). Although these vessels fish all over the world, they likely concentrate efforts in the Atlantic. In 2005, 85 percent of the overall reported Spanish shark catches were from the Atlantic Ocean (Shark Alliance, 2007), suggesting the Eastern Atlantic DPS of scalloped hammerhead sharks may be at risk from overutilization by these top EU shark fishing nations.

The threat of overutilization by artisanal fisheries was identified as a moderate risk to the extinction of the scalloped hammerhead shark, but is projected to increase under the weakly regulated and enforced fisheries of West Africa to match the increasing demand for food/protein in this region. In fact, estimates of per capita fish consumption is expected to increase from 2011–2021 in all continents except for Africa, where the population is growing faster than the supply (FAO, 2012). In the Sub Regional Fisheries Commission (SRFC) member countries (Cape-Verde, Gambia, Guinea, Guinea-Bissau, Mauritania, Senegal, and Sierra Leone), the population is predicted to increase from 35 million (in 2007) to around 76 million by 2050 (Diop and Dossa, 2011). The fact that around 78.4 percent of the population currently lives within 100 km of the coast means that there will likely be higher demand and fishing pressure on marine resources as the population continues to grow (Diop and Dossa, 2011). Already, around 96 percent of the fish stocks in the Eastern Central Atlantic are considered fully to overexploited (FAO, 2012). Because many of these West African countries depend on fish for dietary protein but also, as it relates to scalloped hammerhead sharks, as a source of income, the threat of overutilization is not likely to decrease.

According to FAO (2012), Africa is the continent with the highest proportion of its fleet operating in inland waters (42 percent), suggesting juveniles and neonates of this DPS may be in the most danger. And, in fact, large artisanal fisheries in Mauritania have been documented fishing great quantities of juvenile scalloped hammerhead sharks using driftnets and fixed gillnets (CITES, 2010), with *S. lewini* also caught in large numbers in the sciaenid fishery operating in this region. In 2010, the first year that it provided capture production statistics to FAO, Mauritania reported a total catch of 257 mt of *S. lewini,* the highest amount reported by any one country since 2003.

According to Diop and Dossa (2011), shark fishing has occurred in the SRFC member countries for around 30 years. Shark fisheries and trade in this region first originated in Gambia, but soon spread throughout the region in the 1980s and 1990s, as the development and demand from the worldwide fin market increased. From 1994 to 2005, shark catch reached maximum levels, with a continued increase in the number of boats, better fishing gear, and more people entering the fishery, especially in the artisanal fishing sector. Before 1989, artisanal catch was less than 4,000 mt (Diop and Dossa, 2011). However,

from 1990 to 2005, catch increased dramatically from 5,000 mt to over 26,000 mt, as did the level of fishing effort (Diop and Dossa, 2011). Including estimates of bycatch from the industrial fishing fleet brings this number over 30,000 mt in 2005 (however, discards of shark carcasses at sea were not included in bycatch estimates, suggesting bycatch may be underestimated) (Diop and Dossa, 2011). In the SRFC region, an industry focused on the fishing activities, processing, and sale of shark products became well established. However, since 2005, there has been a significant and ongoing decrease in shark landings, with an observed extirpation of some species, and a scarcity of others, such as large hammerhead sharks (Diop and Dossa, 2011), indicating overutilization of the resource. From 2005 to 2008, shark landings dropped by more than 50 percent (Diop and Dossa, 2011). In 2010, the number of artisanal fishing vessels that landed elasmobranches in the SRFC zone was estimated to be around 2,500 vessels, with 1,300 of those specializing in catching sharks (Diop and Dossa, 2011).

Although species-specific data from this region are relatively poor, due to the lack of detailed catch reporting in many of the developing African countries, the ERA team concluded, and we agree, that the available commercial information, observations on fishing activities, and catch trends suggest that the threat of overutilization alone is likely to contribute significantly to risk of extinction for the Eastern Atlantic DPS.

Indo-West Pacific DPS

The ERA team identified the threat of overutilization by industrial/commercial and artisanal fisheries as a high risk to the extinction of the Indo-West Pacific DPS, with the threat projected to increase in the foreseeable future. High levels of commercial fishing that target sharks or catch them as bycatch occur in this DPS. Unfortunately, few studies on the specific abundance of *S. lewini* have been conducted in this DPS, making it difficult to determine the rate of exploitation of this species. One study, off the coast of Oman, found *S. lewini* to be among the most commonly encountered species in commercial landings from 2002 to 2003 (Henderson *et al.,* 2007). However, in 2003, *S. lewini* experienced a notable decline in relative abundance and, along with other large pelagic sharks, was displaced by smaller elasmobranch species (a trend also reported by informal interviews with fisherman) (Henderson *et al.,* 2007). Off East Lombok, in Indonesia, data provided to the FAO also suggest potential declines in the population as the proportion of scalloped hammerheads in the Tanjung Luar artisanal shark longline fishery catch decreased from 15 percent to 2 percent over the period of 2001 to 2011 (FAO, 2013). Additionally, CPUE data from South Africa and Australia shark control programs indicate significant declines (over 90 percent) of local scalloped hammerhead populations in this DPS, most likely a result from overharvesting, although it should be noted that these shark control programs were also assessed to have at least a medium causative impact on these localized depletions.

In other waters of this DPS, such as off the coasts of Maldives, Kenya, Mauritius, Seychelles, and the United Republic of Tanzania, shark populations are presumed to be fully to over-exploited (de Young, 2006). Likely contributing to the overexploitation of shark populations is the vast number of tuna fisheries prevalent within the range of this DPS, which are known to take substantial amounts of sharks as bycatch. In the Republic of the Marshall Islands EEZ, the tuna fishery alone accounted for annual longline catches ranging from 1,583 to 2,274 mt of sharks (over the period of 2005–2009) (Bromhead *et al.,* 2012). The tuna purse seine fleet is also very active in this region and contributes to the incidental catch of scalloped hammerhead sharks. The recent addition of fleets entering the Western and Central Pacific Fishery Commission (WCPFC) tropical fishery have brought the number of purse seine vessels up to 280, the highest it has been since 1972 (Williams and Terawasi, 2011). This is especially troubling given the species' susceptibility to being caught in large numbers in purse seine nets (Román-Verdesoto and Orozco-Zöller, 2005), although recent WCPFC observer data suggest otherwise (SPC, 2010). In fact, the WCPFC observer data, collected from 1994–2009, indicate that longline sets may pose more of a threat to non-target shark species than purse-seine sets in this convention area, but in terms of hammerhead sharks, observers reported only negligible catch but with high rates of finning in both types of sets (SPC, 2010). However, some fisheries operating in the WCPFC Convention Area have not been observed, such as the Chinese Taipei small scale tuna longline fleet, which reported a significant catch of 365 mt (preliminary estimate) of scalloped hammerhead sharks in the Convention Area in 2010 (Shark Year Magazine, 2011), and suggests reliance on observer data alone may not be a good indicator of scalloped hammerhead catch in this region.

Currently, the exact extent of fishing on this DPS by WCPFC vessels is unknown, as the WCPFC has only just recently designated hammerheads as key shark species for data collection (WCPFC, 2011) and many Cooperating Commission Member (CMM) and Cooperating Non-Member fleets have yet to provide this catch data, including fleets from among the top 20 countries reporting Pacific shark catches to the FAO. As of 2012, the CMMs that reported specific catches of hammerheads from 2011 in the WCPFC convention area included Australia, Papua New Guinea, Fiji, Chinese Taipei, and the European Union. The European Union reported only negligible catch of hammerheads, with Fiji and Australia reporting zero catches of scalloped hammerhead sharks. Papua New Guinea, which currently has an active shark longline fishery that is managed separately from its tuna longline fishery, reported catch from its domestic shark fishery to the WCPFC. This shark fishery operates entirely within Papua New Guinea's national waters, and is limited to 9 vessels, setting 1,200 hooks per day with a total allowable catch of 2,000 mt dressed weight per year (Usu *et al.,* 2012). This fishery has seen substantial expansion since 2000, when there was only one active vessel with a reported catch of 143 sharks. However, in the last 4 years, an average of 7 vessels has actively fished for sharks, with an average catch of 56,528 sharks (Usu *et al.,* 2012). In 2011, there were 9 active shark longline vessels, reporting the highest overall effort yet (27,934 hundred hooks), and subsequently reporting the highest catches of sharks to date (1,479.66 mt) (Usu *et al.,* 2012). Hammerhead shark species comprised only 1.5 percent of the catch (22.34 mt), which was a decrease of 43 percent from the previous year and suggests that the intensive and targeted shark fishing effort may be contributing to the hammerhead population decline in these waters.

Many fisheries in this region are also driven primarily by the lucrative trade in shark fins. For example, in northern Madagascar, Robinson and Sauer (2011) documented an artisanal fishery that targets sharks primarily for their fins and discards the carcasses. Two shark families comprised the majority of the artisanal landings: Carcharhinidae accounted for 69 percent of the species and Sphyrnidae accounted for 24 percent (Robinson and Sauer, 2011). *S. lewini* was the most common species in

the Sphyrnidae landings. In addition, many of these fishers operated in water shallower than 100 m and, consequently, over 96 percent of their scalloped hammerhead catch was comprised of immature individuals (Robinson and Sauer, 2011). Similarly, the shark fisheries operating in Antongil Bay in northeastern Madagascar commonly land only fins, rather than whole sharks, with the scalloped hammerhead shark as the most represented species in the shark fishery (Doukakis *et al.,* 2011). Both adults, including pregnant females, and juveniles are harvested in the small and large-mesh artisanal gillnet and traditional beach seine fisheries, suggesting largely unregulated and targeted fishing of scalloped hammerhead sharks in a potential breeding ground (Doukakis *et al.,* 2011).

Furthermore, four of the top five exporters of shark fins to Hong Kong (Singapore, Taiwan, Indonesia, and the United Arab Emirates) are located in this DPS' range. In 2008, these countries accounted for around 34 percent (or 3,384 mt) of the total exports of shark fins (both frozen and dried). Therefore, with the increased number of tuna fleets, evidence of declines in shark catch and populations in this DPS range, as well as the popularity of the scalloped hammerhead shark in the fin trade, the ERA team agreed that the threat of overutilization alone is likely to contribute significantly to the risk of extinction of the Indo-West Pacific DPS.

Central Pacific DPS

The ERA team identified the threat of overutilization by industrial/commercial fisheries as a moderate risk to the extinction of the Central Pacific DPS, with the threat projected to remain the same in the foreseeable future. Currently, scalloped hammerheads in this region are mainly caught as bycatch by pelagic longline and purse seine fleets. The Hawaii-based pelagic longline fishery has been in operation since approximately 1917, and underwent considerable expansion in the late 1980s to become the largest fishery in the state (Boggs and Ito, 1993). This fishery currently targets tunas and billfish and catches are frequently documented by mandatory observers (100 percent coverage for shallow-set sector and 25 percent for deep-set sector). From 1995–2006, the observer data indicated a very low catch of scalloped hammerhead sharks (56 individuals on 26,507 sets total, both fishery sectors combined). More recent observer data (2009–2011) from this fishery confirm that scalloped hammerhead sharks continue to be a very rare catch, commensurate with the earlier time period (Walsh *et al.,* 2009; Walsh personal communication, 2012). In non-longline catch, hammerhead shark species are also rare, with a total of 11 sharks caught from 1990–1994 and 1995–1999, 6 caught from 2000–2004, 17 caught from 2005–2009, and 6 caught from 2010–2011 (Seki and Kokubun personal communication, 2012). Although the ERA team identified overutilization by commercial fisheries as a threat, it ranked it as a moderate risk, one that would contribute significantly to risk of extinction only in combination with other factors, such as low and decreasing abundance or inadequate regulatory mechanisms. We do not believe that the observed low catch of this DPS is due to low population numbers since, as previously mentioned, abundance is high in this area due in part to the DPS' productive nursery grounds. Therefore, the low catch of *S. lewini* is likely due to the strict management and regulation of these commercial fisheries within this DPS range (see *The Inadequacy of Existing Regulatory Mechanisms* section below). As such, we conclude that the available data suggest that the threat of overutilization by commercial fisheries is ameliorated by high population abundance and effective existing management measures. We also agree with the ERA team's finding that the adequacy of regulatory mechanisms in minimizing the extinction risk of this DPS will only increase in the next 50 years, making it unlikely that the threat of overutilization will be a greater risk to the DPS' continued existence in the foreseeable future.

Eastern Pacific DPS

The ERA team identified the threat of overutilization by industrial/commercial fisheries and artisanal fisheries as a high risk to the extinction of the Eastern Pacific DPS, with the threat projected to increase in the foreseeable future. Although abundance data are lacking in this area, information from commercial and artisanal fisheries suggests heavy exploitation of this DPS. As an example, in central Mexico, the shark fishery, which began in the early 1940s, grew from catches of less than 5,000 mt in the early 1960s to catches of 25,000 mt in the late 1970s, and reached maximum exploitation in the 1980s and 1990s (Pérez-Jiménez *et al.,* 2005). During this time, scalloped hammerheads were an important small shark species that was routinely caught on the southern coast of Sinaloa (Pérez-Jiménez *et al.,* 2005; Bizzarro *et al.,* 2009). From 1998–1999, scalloped hammerhead sharks comprised 54.4 percent of the elasmobranch catch and 43.1 percent of the total recorded catch (n = 1,584 *S. lewini* individuals) based on surveys from 28 Sinaloa artisanal fishing sites (Bizzarro *et al.,* 2009). In 2006, elasmobranch landings from this area comprised 16.5 percent of the national elasmobranch production, the most of any Mexican state, indicating *S. lewini* as a popular fished species in the Mexican shark fishery. *S. lewini* is also an important shark species in the artisanal fisheries operating elsewhere along the Mexican Pacific coast. From 2004 to 2005, *S. lewini* comprised 64 percent of the artisanal shark catch south of Oaxaca, Mexico (CITES, 2012). In the Gulf of Tehuantepec, scalloped hammerhead sharks constitute the second most important shark species targeted by Mexican fishers, comprising around 29 percent of the total shark catch from this region (INP, 2006). In fact, from 1996 to 2003, a total of 10,919 individual scalloped hammerhead sharks were landed from this area and brought to port in the Mexican state of Chiapas (INP, 2006), where *S. lewini* and *C. falciformis* represent 89.3 percent of the shark catch (CITES, 2012).

In Ecuador, sharks are mainly caught as incidental catch in a variety of fishing gear, including pelagic and bottom longlines, and drift and set gill nets, with scalloped hammerheads used primarily for the fin trade. A recent study by Jacquet *et al.* (2008) found that Ecuadorian mainland shark landings have been grossly underestimated. Through a reconstruction of catches by small-scale and industrial fishers using government reports and grey literature, Jacquet *et al.* (2008) estimated Ecuador mainland landings to be 6,868 mt (average) per year from 1979–2004, with small-scale fisheries representing 93 percent of the total landings. For the period of 1991–2004, the reconstructed estimates were 3.6 times greater than what was reported to the FAO. For the years following the study, Ecuadorian records from small-scale fisheries show significantly lower catches of the hammerhead complex and no clear trend. In 2004, total combined landings from ten of Ecuador's main small-scale fishing ports were approximately 149 mt. In 2005, this number decreased by about 67 percent to 49 mt but subsequently increased in the following years to reach a peak of 327 mt in 2008. In 2009, landings decreased again by around 71 percent, but tripled the following year to reach approximately 304 mt of hammerhead sharks in 2010 (INP, 2010).

In Costa Rica, shark catches reported by the artisanal and longline fisheries have shown a dramatic decline

(approximately 50 percent) after reaching a maximum of 5,000 mt in 2000 (SINAC, 2012). According to the Costa Rican Institute of Fishing and Aquaculture, the estimated total catch of *S. lewini* by the coastal artisanal and longline fleet from 2004–2007 was 823 mt, which represented 3 percent of the national Costa Rican total catch of sharks for these years (SINAC, 2012).

Of major concern is that many of the artisanal fishers from the Eastern Pacific region are targeting schools of immature *S. lewini* due to the profitability of the younger shark meat (Arriatti, 2011), and likely negatively affecting recruitment to this DPS. In Panama, directed artisanal fishing for hammerheads has been documented in coastal nursery areas, with artisanal gillnet fishery catches dominated by neonate and juvenile *S. lewini* (Arriatti, 2011). Likewise, in Costa Rica, many of the identified nursery grounds for scalloped hammerheads are also popular elasmobranch fishing grounds and are heavily fished by gillnets (Zanella *et al.,* 2009). From 2006 to 2007, artisanal fishers operating in the Gulf of Nicoya (central Pacific coast of Costa Rica) landed a total of 253 scalloped hammerhead sharks. The average total length of these sharks ranged from 75.45–87.92 cm, significantly below the maturity sizes that have been documented for this species (Zanella *et al.,* 2009). In ''Tres Marias'' Islands and Isabel Island in the Central Mexican Pacific, Perez-Jimenez *et al.* (2005) found artisanal fishery catches dominated by immature individuals. Out of 1,178 females and 1,331 males caught from 1995–1996 and 2000–2001, less than 1 percent were mature (Perez-Jimenez *et al.,* 2005). On the coast of Chiapas in Mexico, neonates (≤ 60cm TL) comprised over 40 percent of the Port of Madero catch from 1996–2003 (INP, 2006). Seasonal surveys conducted in Sinaloa, Mexico from 1998–1999 depict an active artisanal fishery that primarily targets early life stages of *S. lewini,* with only four specimens (out of 1,515) measuring > 200 cm stretched TL (Bizzarro *et al.,* 2009). A comparison of landing sizes from this region between 1998–1999 and 2007–2008 revealed a significant decrease in *S. lewini* size, indicating a possible truncation of the size of the local population (Bizzarro *et al.,* 2009). In Michoacán, hammerheads represent 70 percent of the catch, with fishing effort concentrated in breeding areas and directed towards juveniles and pregnant females (CITES, 2012) and reports of the artisanal fisheries filleting the embryos of *S. lewini* for domestic consumption (Smith *et al.,* 2009). Overall, the data suggest heavy fishing pressure in scalloped hammerhead nursery areas by artisanal fisheries, with substantial takes of juveniles and neonates, and possibly pregnant females, of this DPS, which is likely to have devastating effects on the stock structure and size of the population, especially given the low productivity of the species.

Large numbers of scalloped hammerhead sharks are also caught as bycatch in industrial purse seine fisheries operating in the eastern Pacific (Román-Verdesoto and Orozco-Zöller, 2005). Since 1993, observers placed by the Inter-American Tropical Tuna Commission (IATTC) regional fishery management organization (RFMO) have recorded shark bycatch data onboard large purse seiners in the eastern Pacific. Unfortunately, much of this data is aggregated under the category of ''sharks,'' especially data collected prior to 2005. In an effort to improve species identifications in these data, a 1-year shark characteristics sampling program was conducted to quantify at-sea observer misidentification rates. Román-Verdesoto and Orozco-Zöller (2005) used the program results and IATTC observer field notes to provide summaries of the spatial distributions, size composition, and species identification of the IATTC-observed bycatch of sharks in the eastern Pacific Ocean tuna purse-seine fishery. From 1993 to 2004, hammerhead sharks were caught in high numbers as bycatch and were most susceptible to the floating-objects type of purse seine set (Román-Verdesoto and Orozco-Zöller, 2005). From 2001 to 2003, their observed numbers in the tuna purse seine sets increased by approximately 166 percent to reach a maximum of 1,898 individuals. Although specific data on scalloped hammerhead numbers are unavailable, results from the 1-year sampling program suggest that scalloped hammerhead sharks may comprise around 54 percent of the total hammerhead bycatch (Román-Verdesoto and Orozco-Zöller, 2005). The IATTC observer data also revealed that the majority of the bycatch consisted of large hammerhead individuals (>150 cm TL).

Given the available data on catch trends and the heavy fishing effort targeting both juveniles and adults of the species, the ERA team concluded, and we agree, that the threat of overutilization by industrial/commercial and artisanal fisheries alone was likely to contribute significantly to risk of extinction for the Eastern Pacific DPS.

Competition, Disease, and Predation

The ERA team also wanted to examine whether competition, disease, and predation were potential threats to the scalloped hammerhead shark, but after reviewing the available data, ranked these factors as ''no or very low risks,'' meaning these factors are unlikely to contribute significantly to any of the DPS' risk of extinction, either by themselves or in combination with other factors. Scalloped hammerhead sharks are apex predators and opportunistic feeders, with a diet composed of a wide variety of items, including teleosts, cephalopods, crustaceans, and rays (Compagno, 1984; Bush, 2003; Júnior *et al.,* 2009; Noriega *et al.,* 2011). Although there may be some prey species that have experienced population declines, no information exists to indicate that depressed populations of these prey species are negatively affecting the scalloped hammerhead shark abundance. Additionally, discovery of a possibly cryptic species of *Sphyrna* sp. was reported in the northwestern Atlantic (mainly from coastal North Carolina, South Carolina, and Florida) and most recently in the western South Atlantic (Southern Brazil) (Abercrombie *et al.,* 2005; Quattro *et al.,* 2006; Pinhal *et al.,* 2012). This cryptic species is closely related to and morphologically very similar to the scalloped hammerhead shark (*S. lewini*); however, little is known about the life history or abundance of this species. Although it may compete for similar resources as the scalloped hammerhead shark, there are currently no available data to indicate it as a threat to the scalloped hammerhead shark's existence.

Furthermore, no information has been found to indicate that disease is a factor in scalloped hammerhead shark abundance. These sharks likely carry a range of parasites, such as external leeches (*Stilarobdella macrotheca*) and copepods (*Alebion carchariae, A. elegans, Nesippus crypturus, Kroyerina scotterum*); however, they have often been observed visiting parasite cleaning stations (Bester, n.d.) and no data exist to suggest these parasites are affecting *S. lewini* abundance.

Predation is also not thought to be a major threat to scalloped hammerhead abundance numbers. The most significant predator on scalloped hammerhead sharks is likely humans; however larger sharks, including adult *S. lewini,* are known to prey upon injured or smaller scalloped hammerheads. In Kāneʻohe Bay, Oahu, Clarke (1971) observed high predation on pups by adult scalloped

hammerheads. Clarke (1971) also noted that the pup population remained high and suggested that new births may compensate for pup mortalities. Subsequently, Duncan and Holland (2006) examined mortality rates in this bay and estimated juvenile attrition to be 0.85 to 0.93 for the first year of life (includes both natural and fishing mortality, as well as emigration), a relatively high rate for a nursery habitat. However, the authors concluded that weight loss, and not predation, significantly contributed to the high natural mortality of the shark pups, and suggested the popularity of the nursery ground was due to its value as a refuge from predation. In the northwestern Pacific, Liu and Chen (1999) estimated a significantly lower attrition rate for age zero *S. lewini* sharks (0.558/year), with natural mortality rates decreasing even further to 0.279/year for sharks aged 1–15 years. The ERA team noted that there are no major predators of adult scalloped hammerhead sharks.

Based on the available data, we conclude that it is unlikely that the threats of competition, disease, or predation is contributing on its own or in combination with other factors to the extinction risk of any of the six DPSs evaluated.

The Inadequacy of Existing Regulatory Mechanisms

The ERA team evaluated existing regulatory mechanisms to determine whether they may be inadequate to address threats to each of the scalloped hammerhead DPSs. Existing regulatory mechanisms may include Federal, state, and international regulations. Below is a brief description and evaluation of current and relevant domestic and international management measures that affect each scalloped hammerhead shark DPS. More information on these domestic and international management measures can be found in the status review report (Miller *et al.,* 2013).

NW Atlantic & GOM DPS

The Atlantic HMS Management Division within NMFS develops regulations for Atlantic HMS fisheries, and primarily coordinates the management of Atlantic HMS fisheries in Federal waters (domestic) and the high seas (international), while individual states establish regulations for HMS in state waters. The NMFS Atlantic HMS Management Division currently manages 39 species of sharks (excluding spiny dogfish, which is managed jointly by the New England and Mid-Atlantic Fishery Management Councils, and smooth dogfish, which will be managed by the HMS Management Division) under the Consolidated HMS FMP (NMFS, 2006). The management of these sharks is divided into four species groups: large coastal sharks (LCS), small coastal sharks (SCS), pelagic sharks, and prohibited sharks. The LCS complex is further divided into sandbar sharks and non-sandbar sharks, with different management measures for each group. Scalloped hammerhead sharks are currently managed within the non-sandbar LCS complex with established acceptable biological catch levels to control harvest.

Every year, NMFS monitors the different commercial shark quota complexes and will close the fishing season for each fishery after 80 percent of the respective quota has been landed or is projected to be landed. The non-sandbar LCS commercial quota is split between the Gulf of Mexico and the Atlantic regions. One way that NMFS controls and monitors this commercial harvest is by requiring U.S. commercial Atlantic HMS fishers who fish for or sell scalloped hammerhead sharks to have a Federal Atlantic Directed or Incidental shark limited access permit. These permits are administered under a limited access program, and NMFS is no longer issuing new shark permits. Currently, 214 U.S. fishers are permitted to target sharks managed by the HMS Management Division in the Atlantic Ocean and Gulf of Mexico, and an additional 285 fishers are permitted to land sharks incidentally. A directed shark permit allows fishers to retain 36 LCS, including scalloped hammerhead sharks, per vessel per trip whereas an incidental permit allows fisherman to retain up to 3 LCS, including scalloped hammerhead sharks, per vessel per trip. These limits apply to all gear; however, starting in 2011, pelagic longline fishers have been prohibited from retaining, possessing, or landing any hammerhead sharks, including scalloped hammerhead sharks, due to Recommendation 10–08 from the International Commission for the Conservation of Atlantic Tunas (ICCAT) (76 FR 53652; August 29, 2011). In addition to permitting and trip limit requirements, logbook reporting or carrying an observer onboard may be required for selected commercial fishers. The head may be removed and the shark may be gutted and bled, but the shark cannot be filleted or cut into pieces while onboard the vessel.

Scalloped hammerhead sharks may also be retained recreationally with either rod and reel or handline gear. Scalloped hammerheads that are kept in the recreational fishery must have a minimum size of 54 inches (4.5 feet) fork length, and only one shark, which could be a scalloped hammerhead, may be kept per vessel per trip. When NMFS implemented ICCAT's Recommendation 10–08, NMFS prohibited hammerhead sharks, including scalloped hammerhead sharks, from being retained, possessed, or landed by recreational fishermen if there is a tuna, swordfish, or billfish onboard the vessel (76 FR 53652; August 29, 2011). Since 2008, recreational fishers have been required to land all sharks with their head, fins, and tail naturally attached.

Individual state fishery management agencies have authority for managing fishing activity in state waters, which usually extends from zero to three nautical miles (5.6 km) off the coast in most cases, and zero to nine nautical miles (16.7 km) off Texas and the Gulf coast of Florida. In the case of federally permitted shark fishers, fishers are required to follow Federal regulations in all waters, including state waters, unless the state has more restrictive regulations. To aid in enforcement and reduce confusion among fishers, in 2010, the Atlantic States Marine Fisheries Commission, which regulates fisheries in state waters from Maine to Florida, implemented a Coastal Shark Fishery Management Plan that mostly mirrors the Federal regulations for sharks, including scalloped hammerhead sharks. States in the Gulf of Mexico and territories in the Caribbean Sea have also implemented regulations that are mostly the same as the Federal regulations for sharks, including scalloped hammerhead sharks. However, the state of Florida, which has the largest marine recreational fisheries in the United States and the greatest number of HMS angling permits, recently went even further than Federal regulations to protect the scalloped hammerhead shark by prohibiting the harvest, possession, landing, purchasing, selling, or exchanging any or any part of a hammerhead shark (including scalloped, smooth, and great hammerheads) caught in its waters (Florida Fish and Wildlife Conservation Commission, effective January 1, 2012).

The ERA team determined, and we agree, that existing domestic management measures implemented under U.S. Federal and state authorities are adequate to substantially reduce the primary threats contributing to the extinction risk of the NW Atlantic & GOM DPS. The existing regulatory mechanisms, which strictly manage and control exploitation of the species by commercial and recreational fisheries, are likely to contribute significantly to stabilizing and increasing abundance of

this DPS. Based on an analysis of recreational and commercial catch and landings data from the early 1980s through 2005, the Hayes *et al.* (2009) stock assessment showed that a total allowable catch (TAC) of 2,853 scalloped hammerhead sharks would allow for a greater than 70 percent probability of rebuilding the stock within 10 years, an 85 percent probability of rebuilding within 20 years, and a 91 percent probability of rebuilding within 30 years. Under existing Federal shark regulations, the average total scalloped hammerhead shark mortality from 2006–2010 was less than this Hayes *et al.* (2009) TAC recommendation, suggesting current regulatory measures are adequate to protect the scalloped hammerhead shark from risk of extinction. Furthermore, because NMFS made an ''overfished'' and ''overfishing'' status determination of the scalloped hammerhead stock (76 FR 23794; April 28, 2011), it is mandated to implement additional conservation and management measures by 2013, providing additional protection for the scalloped hammerhead shark stock from overexploitation. Proposed conservation efforts are evaluated below in accordance with ESA Section 4(b)(1)(A).

Although the ERA team considered the threat of inadequate regulatory measures as a low risk to the extinction of this scalloped hammerhead shark population, it expressed concerns about the level of IUU fishing of this DPS. Since the mid-1990s, the U.S. Coast Guard has documented Matamoros Mexican vessels illegally fishing in the area surrounding South Padre Island, Texas (Brewster-Geisz and Eytcheson, 2005). The Mexican IUU fishers use gillnet and longline gear to catch sharks for the fin trade, the majority of which are blacktips and hammerheads. Based on data from 2000–2005, Brewster-Geisz and Eytcheson (2005) estimated that Mexican fishers are illegally catching anywhere from 3 to 56 percent of the total U.S. Atlantic commercial shark quota, and between 6 and 108 percent of the Gulf of Mexico regional commercial quota, indicating a high degree of uncertainty in these estimates. Updated data since 2005 show a decrease in the number of detected incursions (Brewster-Geisz *et al.,* 2010); however, the extent of IUU fishing on the scalloped hammerhead sharks in the Gulf of Mexico remains unknown. In 2012, Mexico established an annual shark fishing prohibition in its jurisdictional Gulf of Mexico waters (from May 1 to June 30) (DOF, 2012), which may also help deter future IUU fishing by its fishers, at least during the prohibitive period.

Central & SW Atlantic DPS

In addition to its jurisdiction in NW Atlantic & GOM DPS waters, the United States also has jurisdiction over a very small portion of this DPS range, specifically the U.S. EEZ around Puerto Rico and the U.S. Virgin Islands (as defined in 50 CFR 622.2), where Federal fishing laws apply. NMFS recently published an amendment to the Consolidated HMS FMP which specifically addresses Atlantic HMS fishery management measures in the U.S. Caribbean territories (77 FR 59842; Oct. 1, 2012). Due to substantial differences between some segments of the U.S. Caribbean HMS fisheries and the HMS fisheries that occur off the mainland of the United States (including permit possession, vessel size, availability of processing and cold storage facilities, trip lengths, profit margins, and local consumption of catches), NMFS implemented measures to better manage the traditional small-scale commercial HMS fishing fleet in the U.S. Caribbean Region. Among other things, this rule created an HMS Commercial Caribbean Small Boat (CCSB) permit, which: allows fishing for and sales of big eye, albacore, yellowfin, and skipjack tunas, Atlantic swordfish, and Atlantic sharks within local U.S. Caribbean market; collects HMS landings data through existing territorial government programs; authorizes specific gears; is restricted to vessels less than or equal to 45 feet (13.7 m) length overall all; and may not be held in combination with any other Atlantic HMS vessel permits. However, at this time, fishers who hold the CCSB permit are prohibited from retaining Atlantic sharks, and are restricted to fishing with only rod and reel, handline, and bandit gear under the permit. Both the CCSB and Atlantic HMS regulations will help protect scalloped hammerhead sharks, but only within the U.S. EEZ around Puerto Rico and the U.S. Virgin Islands and from fishers under U.S. jurisdiction.

Many other foreign commercial and artisanal fisheries operate within the range of this DPS, with little to no regulatory oversight, and thus existing regulations are likely inadequate to reduce the most significant threats to the scalloped hammerhead shark population. For example, artisanal gillnet fisheries, known for their substantial bycatch problems, are still active in Central America, with many allowed to operate in inshore nursery areas. Due in large part to the number of sovereign states found in this region, the management of shark species in Central America and the Caribbean remains largely disjointed, with some countries lacking basic fisheries regulations (Kyne *et al.,* 2012). Other countries lack the capabilities to enforce what has already been implemented. The Organization of the Fisheries and Aquaculture Section of the Central American Isthmus (OSPECA) was formed to address this situation by assisting with the development and coordination of fishery management measures in Central America. OSPECA recently approved a common regional finning regulation for eight member countries from the Central American Integration System (SICA) (Belize, Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Nicaragua, and Panama). The regulation specifically requires sharks to be landed with fins still attached for vessels fishing in SICA countries or in international waters flying a SICA country flag. If fins are to be traded in a SICA country, they must be accompanied by a document from the country of origin certifying that they are not the product of finning (Kyne *et al.,* 2012). Other Central American and Caribbean country-specific regulations include the banning or restriction of longlines in certain fishing areas (Bahamas, Belize, Panama), seasonal closures (Guatemala), shark fin bans (Colombia, Mexico, Venezuela) and the prohibition of shark fishing (Bahamas and Honduras). Unfortunately, enforcement of these regulations is weak, with many reports of illegal and unregulated fishing activities. For example, in May 2012, the Honduran navy seized hundreds of shark fins from fishers operating illegally within the borders of its shark sanctuary. As Kyne *et al.* (2012) reports, it is basically common practice to move shark fins across borders for sale in countries where enforcement is essentially lacking in this region.

In South America, Brazil has also banned finning, but continues to find evidence of IUU fishing in its waters. In Belém in May 2012, the Brazilian Institute of Environmental and Renewable Natural Resources (IBAMA) seized around 7.7 mt of illegally obtained dried shark fins intended for export to China (Nickel, 2012). A few months later, IBAMA confiscated more than 5 mt of illegal shark fins in Rio Grande do Norte (Rocha de Medeiros, 2012), suggesting current regulations and enforcement are not adequate to deter or prevent illegal shark finning. In fact, it is estimated that illegal fishing constitutes 32 percent of the Southwest Atlantic region's catch (based on estimates of illegal and unreported catch

averaged over the years of 2000 to 2003; Agnew *et al.,* 2009).

In addition, heavy industrial fishing off the coast of Brazil, with the use of drift gillnets and longlines, remains largely unregulated, as does the intensive artisanal fishery which accounts for about 50 percent of the fishing sector. Brazil currently has regulations limiting the extension of pelagic gillnets and prohibiting trawls in waters less than 3 nautical miles (5.6 km) from the coast; however, as is the case with many regulations affecting this DPS, inadequate enforcement of these laws has led to continued fishing in these inshore nursery areas and resultant observed declines in both adult and juvenile scalloped hammerhead abundance (Amorim et al., 1998; Kotas, 2008; CITES, 2010). Brazil is also presently working on implementing new regulations to enforce recent ICCAT recommendations (Hazin personal communication, 2012). ICCAT is the RFMO responsible for the conservation of tunas and tuna-like species in the Atlantic Ocean and its adjacent seas, and, as mentioned previously, adopted Recommendation 10–08 prohibiting the retention of hammerheads caught in association with ICCAT-managed fisheries. Each Contracting Party to ICCAT is responsible for implementing this recommendation. Many countries within the Central & SW Atlantic DPS range are Contracting Parties to ICCAT, including Brazil, Venezuela, Panama, Honduras, Nicaragua, Belize, Trinidad & Tobago, Barbados, and St Vincent & the Grenadines. ICCAT Recommendation 10–08 includes a special exception for developing coastal States, allowing them to retain hammerhead sharks for local consumption provided that they report their catch data to ICCAT, endeavor not to increase catches of hammerhead sharks, and take the necessary measures to ensure that no hammerhead parts enter international trade. As this exception allows hammerheads to be retained under certain circumstances, it may provide a lesser degree of protection for hammerhead sharks in the developing coastal States that choose to take advantage of the exception.

Given the information above, the ERA team ranked both IUU fishing and the inadequacy of current regulatory mechanisms as moderate risks. We agree that these factors, in combination with others (such as overutilization and low species productivity), likely contribute significantly to the Central & SW Atlantic DPS risk of extinction.

Eastern Atlantic DPS

The ICCAT convention area also covers the range of the Eastern Atlantic DPS, providing some protection for scalloped hammerheads; however, again, given the special exception available to developing coastal States for local consumption, Recommendation 10–08 provides a lesser degree of protection for hammerhead sharks in those fisheries. Given this exception, the management measures that may be implemented to achieve the ICCAT recommendation may not be adequate to protect the shark from overutilization. Within the range of this DPS, many of the countries that would qualify under this exemption, mainly those countries along the west coast of Africa, also have weak or poorly enforced country-specific shark fisheries regulations. In other words, these countries will be able to continue fishing for scalloped hammerhead sharks with little to no regulation on the harvest of the species and existing regulatory mechanisms in these areas are not considered adequate to control or reduce the primary threats to this DPS.

In Europe, the European Parliament recently passed a proposal prohibiting the removal of shark fins by all vessels in EU waters and by all EU-registered vessels operating anywhere in the world. Previously, the EU prohibited shark finning, but allowed fins and bodies to be landed in different ports, resulting in enforcement difficulties, and allowed justified exceptions and special permits for finning, essentially diminishing the effectiveness of the finning ban. In 2009, the EU accounted for up to 17 percent of the global shark catch, and is the largest exporter of shark products to markets in mainland China and Hong Kong. Therefore, in an effort to close the loopholes in the original shark fin regulations and discourage the wasteful practice of finning, the European Parliament passed the proposal requiring fins be attached to landed sharks. This proposal is expected to be approved by member states, which will make the draft law definitive.

Many individual European countries have already implemented measures to stop the practice of finning and conserve shark populations. For example, England and Wales banned finning in 2009 and no longer issue special permits for finning exceptions. France prohibits on-board processing of sharks, and Spain recently passed a regulation in 2011 that prohibits the capture, injury, trade, import and export of scalloped hammerhead sharks, with a periodic evaluation of their conservation status. Given that Spain is Europe's top shark fishing nation, accounting for 7.3 percent of the global shark catch, and was the world's largest exporter of shark fins to Hong Kong in 2008, this new regulation should provide significant protection for scalloped hammerhead sharks from Spanish fishing vessels.

Although regulations in Europe appear to be moving towards the sustainable use and conservation of shark species, these strict and enforceable regulations do not extend farther south in the Eastern Atlantic, where the majority of scalloped hammerhead sharks are caught. Some western African countries have attempted to impose restrictions on shark fishing; however, these regulations either have exceptions, loopholes, or poor enforcement. For example, Mauritania has created a 6,000 km^2 coastal sanctuary for sharks and rays, prohibiting targeted shark fishing in this region; however, sharks, such as the scalloped hammerhead, may be caught as bycatch in nets. Many other countries, such as Namibia, Guinea, Cape-Verde, Sierra Leone, and Gambia, have shark finning bans, but even with this regulation, scalloped hammerhead sharks are may be caught with little to no restrictions on harvest numbers. According to Diop and Dossa (2011), fishing in the SRFC region now occurs year-round, including during shark breeding season, and, as such, both pregnant and juvenile shark species may be fished, with shark fins from fetuses included on balance sheets at landing areas. Many of these state-level management measures also lack standardization at the regional level (Diop and Dossa, 2011), which weakens some of their effectiveness. For example, Sierra Leone and Guinea both require shark fishing licenses; however, these licenses are much cheaper in Sierra Leone, and as a result, fishers from Guinea fish for sharks in Sierra Leone (Diop and Dossa, 2011). Also, although many of these countries have recently adopted FAO recommended National Plans of Action—Sharks, their shark fishery management plans are still in the early implementation phase, and with few resources for monitoring and managing shark fisheries, the benefits to sharks from these regulatory mechanisms (such as reducing the threat of overutilization) have yet to be realized (Diop and Dossa, 2011).

In addition, reports of IUU fishing are prevalent in the waters off West Africa and account for around 37 percent of the region's catch, the highest regional estimate of illegal fishing worldwide (Agnew *et al.,* 2009; EJF, 2012). From

January 2010 to July 2012, the UK-based non-governmental organization Environmental Justice Foundation (EJF) conducted a surveillance project in southern Sierra Leone to determine the extent of IUU fishing in waters off West Africa (EJF, 2012). The EJF staff received 252 reports of illegal fishing by industrial vessels in inshore areas, 90 percent of which were bottom trawlers, with many vessels exporting their catches to Europe and East Asia (EJF, 2012). The EJF (2012) surveillance also found these pirate industrial fishing vessels operating inside exclusion zones, using prohibited fishing gear, refusing to stop for patrols, attacking local fishers and destroying their gear, and fleeing to neighboring countries to avoid sanctions. Due to a lack of resources, many West African countries are unable to provide effective or, for that matter, any enforcement, with some countries even lacking basic monitoring systems. These deficiencies further increase the countries' susceptibility to IUU fishing, resulting in heavy unregulated fishing pressure and likely overexploitation of their fisheries.

Overall, the ERA team ranked the inadequacy of existing regulatory measures and IUU fishing as moderate risks to the entire Eastern Atlantic DPS. However, since this DPS is most abundant off waters of West Africa, we conclude that the threats concentrated in this area would not be greatly minimized by increased conservation measures within European waters. The available data suggest that illegal fishing is a serious and rampant problem in West African waters, and with lack of enforcement of existing regulations and weak management of the fisheries in this area, as evidenced by the observed substantial and largely unregulated catches of both adult and juvenile hammerheads by artisanal fishers in this region, we agree with ERA team's findings and conclude that the combination of both the inadequacy of existing regulatory measures and IUU fishing are contributing significantly to the risk of extinction of this DPS. The ERA team concluded that the threat of IUU fishing is also projected to increase as current regulatory mechanisms are expected to remain the same in the foreseeable future. We agree that the threat of IUU fishing is likely to increase in the next 50 years without effective fishery management regulations and enforcement in this DPS range.

Indo-West Pacific DPS

Multiple RFMOs cover the Indo-West Pacific DPS area, including the Indian Ocean Tuna Commission in the Indian Ocean and the WCPFC in the western Pacific. Currently, these RFMOs require the full utilization of any retained catches of sharks, with a regulation that onboard fins cannot weigh more than 5 percent of the weight of the sharks. These regulations are aimed at curbing the practice of shark finning, but do not prohibit the fishing of sharks. In addition, these regulations may not even be effective in stopping finning of scalloped hammerheads, as a recent study found the scalloped hammerhead shark to have an average wet-fin-to-round-mass ratio of only 2.13 percent (n=81; Biery and Pauly, 2012). This ratio suggests that fishing vessels operating in these RFMO convention areas would be able to land more scalloped hammerhead shark fins than bodies and still pass inspection. There are no scalloped hammerhead-specific RFMO management measures in place for this region, even though this DPS is heavily fished. Subsequently, this species has seen population declines off the coasts of South Africa and Australia, so much so that in 2012, New South Wales listed it as an endangered species.

Few countries within the Indian Ocean have regulations aimed at controlling the exploitation of shark species. Off northern Madagascar, where there is an active artisanal fin fishery, sharks are an open access resource, with no restrictions on gear, established quotas, or fishing area closures (Robinson and Sauer, 2011). On the other hand, Oman, Seychelles, Australia, South Africa, and Taiwan all have measures to prevent the waste of shark parts and discourage finning. The Maldives have even designated their waters as a shark sanctuary. However, many of the top shark fishing nations and world's exporters of fins are located within the range of this DPS, and have little to no regulation (or enforcement) of their shark fisheries. For example, Indonesia, which is the top shark fishing nation in the world, does not currently have restrictions pertaining to shark fishing or finning. Indonesian small-scale fisheries, which account for around 90 percent of the total fisheries production, are not required to have fishing permits (Varkey *et al.,* 2010), nor are their vessels likely to have insulated fish holds or refrigeration units (Tull, 2009), increasing the incentive for shark finning by this sector (Lack and Sant, 2012). Ultimately, their fishing activities remain largely unreported (Varkey *et al.,* 2010), which suggests that the estimates of Indonesian shark catches are greatly underestimated. In fact, in Raja Ampat, an archipelago in Eastern Indonesia, Varkey *et al.* (2010) estimated that 44 percent of the total shark catch in 2006 was unreported (including small-scale and commercial fisheries unreported catch and IUU fishing).

Although Indonesia adopted an FAO recommended shark conservation plan (National Plan of Action—Shark) in 2010, due to budget constraints, it can only focus its implementation of key conservation actions in one area, East Lombok (Satria *et al.* 2011). The current Indonesian regulations that pertain to sharks are limited to those needed to conform to international agreements (such as trade controls for certain species listed by CITES (e.g. whale shark) or prescribed by RFMOs) (Fischer *et al.,* 2012). Due to this historical and current absence of shark management measures, especially in the small-scale fisheries sector, many of the larger shark species in Indonesian waters have already been severely overfished. In the late 1990s, Indonesian fishers noticed this decline in shark species and began moving south from the South China Sea and Gulf of Thailand to the waters of northern Australia in order to hunt for shark fins (Field *et al.,* 2009). After 2001, Australian Customs patrol reported a large increase in the number of IUU vessel sightings, mainly from Indonesia, with a peak occurring in late 2005 and early 2006 (Field *et al.,* 2009). During 2006, more than 4,000 small traditional vessels were spotted by aerial surveys, with an average of 22 IUU vessels fishing per day (Field *et al.,* 2009). Since this peak, there has been a decline in IUU fishing in Australian waters, thought to be due to exhaustion of stocks in easily accessible regions near the Australian EEZ, as well as international government agreements and domestic policies (Field *et al.,* 2009). Between July 2008 and June 2012, only 60 Indonesian vessels targeting sharks were apprehended (Lack and Sant, 2012). Because illegal shark fishing is often unreported, there is a lack of information available on the species composition of the IUU shark catch. However, using a small collection of shark fins that were confiscated from IUU fishers in northern Australian waters, the Commonwealth Scientific and Industrial Research Organisation identified that 8.8 percent of the illegal fins belonged to *S. lewini.* Only one other shark species, the whitecheek shark (*Carcharhinus dussumieri*), was a source of more fins (27.9 percent) (Lack and Sant, 2008).

In addition to within the Australian EEZ, IUU fishing, especially for shark fins, has been reported in other waters throughout this DPS range. The following are documented cases of IUU fishing as compiled by Paul (2009). In 2008, off the coast of Africa, a

Namibian-flagged fishing vessel was found fishing illegally in Mozambican waters, with 43 mt of sharks and 4 mt of shark fins onboard. In 2009, a Taiwanese-flagged fishing trawler was found operating illegally in the South Africa EEZ with 1.6 mt of shark fins onboard without the corresponding carcasses. Also in 2009, 250 trawlers were found to be poaching sharks in coastal areas in the Bay of Bengal with the purpose of smuggling the sharks to Myanmar and Bangkok by sea. There are also reports of traders exploiting shark populations in the Arabian Gulf due to the lack of United Arab Emirates enforcement of finning regulations. In the Western Pacific, in 2007, a Taiwanese-flagged tuna boat was seized in Palau for IUU fishing and had 94 shark bodies and 650 fins onboard. In 2008, a Chinese-flagged fishing vessel was arrested by the Federated States of Micronesia (FSM) National Police for fishing within the FSM's EEZ. Based on the number of fins found onboard, there should have been a corresponding 9,000 bodies; however, only 1,776 finned shark bodies were counted.

In Somalia, it is estimated that around 700 foreign-owned vessels are operating in Somali waters without proper licenses, and participating in unregulated fishing for highly-valued species like sharks, tunas, and lobsters (HSTF, 2006). A study that provided regional estimates of illegal fishing (using FAO fishing areas as regions) found the Western Central Pacific (Area 71) and Eastern Indian Ocean (Area 57) regions to have relatively high levels of illegal fishing (compared to the rest of the regions), with illegal and unreported catch constituting 34 and 32 percent of the region's catch, respectively (Agnew *et al.,* 2009).

Due to the historical exploitation of shark stocks, current levels of IUU fishing, and noticeable decline in shark stocks, many Pacific Island countries have created shark sanctuaries in their respective waters, including Tokelau, Palau, Marshall Islands, American Samoa, Cook Islands, and French Polynesia; however, enforcement in these waters has proven difficult. Due to the small size of these Pacific Island countries, many simply lack the resources to effectively patrol their expansive oceanic territory. For example, the country of Palau has only one patrol boat to enforce fishing regulations in its 604,000 km² of ocean waters (Turagabeci, 2012). Because of the relatively weak enforcement and potential for large catches of sharks in protected waters, IUU vessels are known to fish in these areas, as mentioned above, and have been found removing thousands of pounds of shark products from these waters (Paul, 2009; AFP, 2012; Turagabeci, 2012). So although the creation of shark sanctuaries is on the rise, especially in areas of known *S. lewini* nursery grounds and ''hot spots'' in this DPS' range, the protections that they afford the Indo-West Pacific DPS may be minimal if IUU fishing is not controlled. Thus, the ERA team ranked the threat of IUU fishing as a high risk and the inadequacy of current regulatory mechanisms as a moderate risk to the extinction of the Indo-West Pacific DPS now. The ERA team predicted that regulatory measures may increase in the foreseeable future, especially in nations that currently lack fishing regulations, but that the threat of IUU fishing of this DPS will remain the same. We agree with the ERA team's findings. Although nations may implement new, or further strengthen existing, fishery management measures that may help protect this DPS from overutilization, without effective enforcement of these regulations, the benefits of these measures may not be realized.

Central Pacific DPS

Significant fishery management measures in the Central Pacific help to protect this DPS from overfishing. As there are no directed shark fisheries on this DPS, the biggest threat to the scalloped hammerhead sharks comes from the Hawaii-based pelagic longline fishery. This fishery, the largest in the state, currently targets tunas and billfish and is managed under the auspices of the WPFMC. Due to the mostly unregulated historical take that occurred in this fishery, and the demand to continue fishery operations, the WPFMC implemented strict management controls for this fishery. Although scalloped hammerheads are only caught as bycatch in this longline fishery, the measures that regulate their operations have helped to protect this species from population declines. Some of these regulations include mandatory observers, designated longline buffer zones, areas of prohibited fishing, and periodic closures and effort limits. Since 1995, an observer program has been in place with targeted coverage of 25 percent in the deep-set longline sector and 100 percent in the shallow-set sector. This program has provided valuable information on the number of scalloped hammerheads caught as bycatch in the fishery. Since many protected species can also be found in this DPS' range, the regulations aimed at minimizing interactions with these species also protects scalloped hammerhead sharks. For example, the Northwestern Hawaiian Island (NWHI) Protected Species Zone prohibits longline fishing within a 50 nautical mile (92.6 km) radius from the centers of the Northwestern Hawaiian Islands and atolls. Commercial fishing is also prohibited within the boundaries of the Marine National Monuments. Around the Main Hawaiian Islands, areas have been designated as closed to longline fishing year-round or open only at certain times of the year. These regulations are strongly enforced, with catch and bycatch of species regularly monitored.

Additionally, several regulatory mechanisms ban the practice of finning, which offer a level of protection to this DPS from overutilization for the shark fin trade. The U.S. Shark Conservation Act of 2010 requires that sharks lawfully harvested in Federal waters, including those located in the range of this DPS, and be landed with their fins naturally attached. In 2000, Hawaii made it unlawful to harvest or land shark fins in the state or territorial waters of the state. These regulatory measures have effectively reduced the harvest of sharks from the DPS and export of shark fins from the region to Hong Kong (Clarke *et al.,* 2007). Additionally, in July 2010, the State of Hawaii enacted additional legislation aimed at curbing shark finning (State of Hawaii SB2169), which may further reduce this threat.

Overall, the strict management of the Hawaii-based pelagic longline fisheries, the additional implemented measures aimed at minimizing protected species interactions, and the current catch data from observers and scientists suggest the regulations in place in this region are adequate to protect the Central Pacific DPS from the threat of extinction. Therefore, the ERA team ranked the threat of inadequate current regulatory mechanisms as a low risk and felt it was unlikely to contribute significantly to this DPS' risk of extinction.

Eastern Pacific DPS

Similar to the RFMO regulations found in the Indo-West Pacific DPS, the RFMO that covers the Eastern Pacific DPS area, the Inter-American Tropical Tuna Commission (IATTC), requires the full utilization of any retained catches of sharks, with a regulation that onboard fins cannot weigh more than 5 percent of the weight of the sharks. Again, these regulations are aimed at curbing the practice of shark finning, but do not prohibit the fishing of sharks, and, as mentioned previously, the fin-to-carcass ratio of 5 percent may not even be effective in protecting scalloped hammerhead sharks from being finned. Although there are no scalloped

hammerhead-specific RFMO management measures in place for this DPS, many of the measures implemented by the IATTC are aimed at protecting non-target species caught by tuna purse-seine vessels. In addition, the IATTC encourages the release of live sharks, especially juveniles that are caught incidentally and are not used for food and/or subsistence in fisheries for tunas and tuna-like species. The IATTC also monitors fishing activities, recommending maximum catch limits for longline vessels based on recent stock assessment data and issuing closures to purse-seine vessels in the convention area. Since hammerheads are frequently a bycatch species in purse-seine nets, these closures should provide extra protection for the Eastern Pacific DPS.

In the west-coast based U.S. fisheries, hammerheads are rarely caught. This is likely due to the fact that the core scalloped hammerhead range is located to the south and west of the U.S. West Coast EEZ (Compagno, 1984). Additionally, recent regulations that prohibit shallow longline sets, restrict specific types of fishing gear, and close various areas to fishing have also contributed to the rare catch of hammerheads in the U.S. Pacific fisheries. In 2004, NMFS issued a final rule that prohibited shallow longline sets on the high seas in the Pacific Ocean by vessels managed under the FMP for U.S. West Coast Fisheries for HMS. Vessels under this FMP, however, are permitted to target tunas with deep-set longline gear in the high seas zone outside the U.S. EEZ, but the number participating is small. During the 2009/2010 fishing season, fewer than three vessels, with 100 percent observer coverage, participated in this deep-set pelagic longline fishery (PFMC, 2011). The California/Oregon drift gillnet fishery is another U.S. west-coast based fishery where hammerheads may be caught as bycatch. In this fishery, target species are mainly swordfish and common thresher sharks. The majority of fishing effort takes place from August through January within the southern California Bight, as this fishery is closed from August 15th to November 15th, in an area of approximately 213,000 square miles (551,670 km^2) off the coasts of central California up to Central Oregon for the protection of leatherback sea turtles. Additional closures of this fishery take place from February 1st to April 30th within 25 nautical miles (46.3 km) of the coast, and from May 1st to August 14th within 75 nautical miles (138.9 km). Even during the peak fishing season, observer data indicate that hammerheads are rarely caught in this fishery. From 1990–2012, a total of 8,310 sets were observed with only 50 hammerhead sharks caught over this time period. However, none of the hammerhead sharks were identified as *S. lewini* (SWRO, 2012).

In addition, in January 2011, the U.S. Shark Conservation Act of 2010 was signed into law, effectively banning the practice of shark finning within the U.S. EEZ or on the high seas by U.S. fishing vessels. Previously, the U.S. Pacific fisheries lacked a fins-attached policy, but with the passage of the U.S. Shark Conservation Act, all sharks must be landed with fins naturally attached. Thus, the U.S. regulatory measures aimed at managing the Pacific fisheries, including the Pacific longline and gillnet fisheries, appear adequate to protect this DPS from overutilization by the U.S. west-coast based fisheries.

Many of the Central American countries in the Eastern Pacific also have regulatory mechanisms in place with regard to sharks; however, some are stronger than others. For example, Colombia, Costa Rica, and El Salvador prohibit shark finning. Panama requires industrial fishers to land sharks with fins naturally attached but artisanal fishers may separate the fins from the carcass, as long as they satisfy the 5 percent weight rule. These regulations may help to deter finning, but they do not protect sharks from overfishing.

Although Ecuador has banned directed fishing for sharks in its waters, sharks caught in ''continental'' (i.e., not Galapagos) fisheries may be landed if bycaught. Panama still allows directed artisanal gillnet fishing for juvenile and adult sharks, including *S. lewini* (Arriatti, 2011), as does the Mexican State of Sinaloa, where the most popular gear in the elasmobranch fishery are bottom set gillnets and longlines (Bizzarro *et al.,* 2009). Bottom fixed gillnets are also allowed in the artisanal fishery around ''Tres Marias'' Island and Isabel Island in the Central Mexican Pacific, with bycatch dominated by juvenile *S. lewini* (Perez-Jimenez *et al.,* 2005). Although Mexico is working towards promoting a sustainable shark and ray fishery, the current legislation (NOM–029–PESCA–2006) allows artisanal fishers to target hammerheads with longlines within 10 nm from the shore and reduces the competition with larger commercial longline vessels, which are subsequently restricted to waters 20 nm or more from the shore. The restriction of these larger commercial longline vessels will be beneficial to the artisanal fleet. However, given the artisanal fleets' already substantial fishing effort on sharks (artisanal vessels contribute 40 percent of the marine domestic production and comprise up to 80 percent of the elasmobranch fishing effort; Cartamil *et al.,* 2011), this increase in fishing opportunity may further threaten the Eastern Pacific DPS, especially since 62 percent of the total Mexican domestic shark production comes from the Pacific Ocean (NOM–029–PESCA–2006). In addition, many of the new regulations are not well understood by current Mexican fishers, with very few fishers found to be in compliance with them (Cartamil *et al.,* 2011). Mexico also recently prohibited shark fishing in its Pacific Ocean waters; however, the prohibition period only lasts 3 months (from May 1 to July 31) (DOF, 2012).

More restrictive regulations, such as complete moratoriums on shark fishing, can be found in this DPS range around Honduras and in the Eastern Tropical Pacific Seascape. The Eastern Tropical Pacific Seascape, a two million square kilometer region that encompasses the national waters, coasts, and islands of Colombia, Costa Rica, Ecuador, and Panama, was created to support marine conservation and sustainable use of resources. The Seascape includes the Galapagos, Cocos, and Malpelo Islands, and, although designated as a shark sanctuary, there is evidence of illegal fishing by both local fishers and industrial longliners within many of these marine protected areas. For example, in Cocos Island National Park, off Costa Rica, a ''no take'' zone was established in 1992, yet populations of *S. lewini* continued to decline by an estimated 71 percent from 1992 to 2004 (Myers *et al.,* n.d.). From 1998–2004, Jacquet *et al.* (2008) found Ecuadorian shark fin exports exceeded mainland catches by 44 percent (average of 3,850 mt per year), and suggested that this discrepancy may have been a result of illegal fishing on protected Galapagos sharks. In 2004, this concern over illegal fishing around the Galapagos Islands prompted a ban on the exportation of fins, but only resulted in the establishment of new illegal trade routes and continued exploitation of the scalloped hammerhead shark (CITES, 2010). In 2007, Paul (2009) reports of a sting operation by the Ecuadorian Environmental Police and the Sea Shepherd Conservation Society which resulted in the seizure of 19,018 shark fins that were being smuggled over the border on buses from Ecuador to Peru. The fins were believed to come from protected sharks in the Galapagos Islands. More recently, in November 2011, Colombian environmental

authorities reported a large shark massacre in the Malpelo wildlife sanctuary. The divers counted 10 illegal Costa Rican trawler boats in the wildlife sanctuary and estimated that as many as 2,000 sharks may have been killed for their fins (Brodzinsky, 2011).

Although shark finning is discouraged in the waters of this DPS, the ERA team voiced concerns about the allowed use of fishing gear that is especially effective at catching schools of scalloped hammerhead sharks within inshore and nursery areas in this DPS range. Thus, the ERA team ranked the threat of inadequate current regulatory mechanisms as a moderate risk. Additionally, without stronger enforcement, especially in the marine protected areas in the Eastern Tropical Pacific, the inadequacy of existing regulatory mechanisms will continue to enable the IUU fishing, which was ranked as a threat contributing significantly to this DPS' risk of extinction now and projected to increase in the foreseeable future. We agree with the ERA team's findings.

Other Natural or Man-Made Factors Affecting Its Continued Existence

Many sharks are thought to be biologically vulnerable to overexploitation based on their life history parameters. As mentioned previously, the scalloped hammerhead shark is no exception, with relatively low estimated productivity values (r = 0.028–0.121; Miller *et al.,* 2013). Contributing to the scalloped hammerhead's biological vulnerability is the fact that these sharks are obligate ram ventilators (they must keep moving to ensure a constant supply of oxygenated water) and suffer very high at-vessel fishing mortality in bottom longline fisheries (Morgan and Burgess, 2007; Macbeth *et al.,* 2009). From 1994–2005, NMFS observers calculated that out of 455 scalloped hammerheads caught on commercial bottom longline vessels in the northwest Atlantic and Gulf of Mexico, 91.4 percent were dead when brought aboard (Morgan and Burgess, 2007). Size did not seem to be a factor influencing susceptibility, as 70 percent of the young *S. lewini* (0–65 cm), 95.2 percent of the juveniles (66–137 cm), and 90.9 percent of the adults (>137 cm) suffered at-vessel fishing mortality. Soak time of the longline had a positive effect on the likelihood of death (Morgan and Burgess, 2007), with soak times longer than 4 hours resulting in > 65 percent mortality (Morgan *et al.,* 2009). When soak time was shortened to 1hour, *S. lewini* at-vessel fishing mortality decreased to 12 percent (Lotti, 2011). Lotti (2011) also found that at-vessel fishing mortality was negatively correlated with *S. lewini* length (p = 0.0032) and dissolved oxygen (p = 0.003), with male scalloped hammerheads showing a higher probability of suffering from at-vessel mortality compared to females (p = 0.0265).

Sphyrna spp. also suffer high mortality in beach net programs (Reid and Krogh, 1992; Dudley and Simpfendorfer, 2006). In a study examining the protective shark mesh program in New South Wales, Australia, *Sphyrna* spp. was the taxonomic group with the lowest net survival rates. The nets used in the protective mesh program were 150 m long and 6 m deep, with a mesh size of 50–60 cm and soak time generally between 12 and 48 hours. Out of the 2,031 hammerheads caught by this program (from 1972–1990), only 1.7 percent were alive when cleared from the nets (Reid and Krogh, 1992). Thus, due to the scalloped hammerhead's high at-vessel fishing mortality on a variety of fishing gear, and the difficulty of implementing or enforcing measures to mitigate this mortality, the ERA team ranked this biological vulnerability as contributing significantly to the risk of extinction of each of the scalloped hammerhead shark DPSs. We agree that the species' high at-vessel mortality may be a significant threat to the species, but only in combination with other factors, such as low abundance, heavy fishing pressure, or inadequate regulatory mechanisms that do not take into account this biological vulnerability in the development of fishery management measures. Therefore, we conclude that the scalloped hammerhead's high at-vessel fishing mortality contributes a greater risk of extinction that may be cause for concern to those DPSs where abundance is low and decreasing and overutilization and/or regulatory mechanisms are significant threats (i.e., Central & SW Atlantic DPS, Eastern Atlantic DPS, Indo-West Pacific DPS, and Eastern Pacific DPS).

Another threat the ERA team identified as affecting the continued existence of *S. lewini* is the shark's schooling behavior. This schooling behavior increases the shark's likelihood of being caught in large numbers. For example, fishers in Costa Rica were documented using gillnets in shallow waters to target schools of juveniles and neonates in these nursery areas (Zanella *et al.,* 2009). In Brazil, schools of neonates and juveniles are caught in large numbers by coastal gillnets and recreational fishers in inshore waters, and subsequently their abundance has significantly decreased over time (CITES, 2010). Off South Africa, Dudley and Simpfendorfer (2006) reported significant catches of newborn *S. lewini* by prawn trawlers, with estimates of 3,288 sharks in 1989, and 1,742 sharks in 1992. This schooling behavior also makes the species a popular target for illegal fishing activity, with fishers looking to catch large numbers of scalloped hammerhead sharks (both adult and juveniles) quickly and with relatively little effort. In the Malpelo wildlife sanctuary, divers had reported sightings of schools of more than 200 hammerhead sharks before the sanctuary became a recent target of IUU fishing vessels (Brodzinsky, 2011). Because this schooling behavior provides greater access to large numbers of scalloped hammerheads, the likelihood of this species being overfished greatly increases. Thus, the ERA team ranked the schooling behavior as a moderate risk for most of the DPSs, a factor that, in combination with others, such as IUU fishing, contributes significantly to the DPS' risk of extinction. In the Eastern Pacific DPS, the ERA team ranked this schooling behavior as a high risk based on reports of frequent IUU fishing on scalloped hammerhead schools in protected waters and the evidence of heavy inshore fishing pressure on schools of juveniles and neonates in nursery grounds. We agree with the ERA team's findings.

Overall Risk Summary

NW Atlantic & GOM DPS

The ERA team concluded, and we agree, that the NW Atlantic & GOM DPS is at a ''low'' risk of extinction throughout all of its range, now and in the foreseeable future. Although the ERA team had some concerns about the significant decline in absolute abundance from fisheries, they concluded that the population has a high likelihood of rebuilding because of stronger fishery management measures and is unlikely to be at risk of extinction due to trends in abundance, productivity, spatial structure or diversity now or in the foreseeable future. Likelihood points attributed to the current level of extinction risk categories are as follows: No or Very Low Risk (6/50), Low Risk (20/50), Moderate Risk (17/50), High Risk (7/50). None of the team members placed a likelihood point in the ''Very high risk'' category for the overall level of extinction risk now or in the foreseeable future, indicating their strong certainty that the DPS is not, nor will it be, at a very high risk of extinction. Likelihood

points attributed to the other categories for the level of extinction risk in the foreseeable future are as follows: No or Very Low Risk (11/50), Low Risk (26/50), Moderate Risk (12/50), High Risk (1/50). Based on the likelihood point distributions, the team was fairly certain that the DPS currently has a low to moderate risk of extinction. However, the difference of only three likelihood points separating these two risk categories indicates a level of uncertainty as to the severity of the current threats and demographic risks. This level of uncertainty diminishes in the foreseeable future, with the increased number and majority of likelihood points for the low risk category.

Central & SW Atlantic DPS

The ERA team concluded, and we agree, that the Central & SW Atlantic DPS is at a ''moderate'' risk of extinction throughout all of its range, now and in the foreseeable future. The ERA team agreed that the DPS is on a trajectory approaching a level of abundance and productivity that places its current and future persistence in question. Given the combination of threats including the inadequacy of current regulatory mechanisms, the reports of heavy fishing, the high at-vessel mortality rate, and the projected increase of commercial, artisanal, and IUU fishing, the team does not envision a reversal of demographic trends in the foreseeable future that would lessen its risk of extinction. Likelihood points attributed to the categories for the current level of extinction risk are as follows: Low Risk (8/50), Moderate Risk (25/50), High Risk (14/50), and Very High Risk (3/50). None of the team members placed a likelihood point in the ''No or very low risk'' category for the overall level of extinction risk now or in the foreseeable future, indicating their strong certainty that the DPS is, and will continue to be, at some risk of extinction. Likelihood points attributed to the other categories for the level of extinction risk in the foreseeable future are as follows: Low Risk (8/50), Moderate Risk (20/50), High Risk (15/50), and Very High Risk (7/50). Based on the likelihood point distributions, the team was fairly certain that the DPS has a moderate risk of extinction now, receiving half of the votes, but expressed some uncertainty regarding the future level of extinction risk, increasing the number of likelihood points in the high and very high risk categories.

Eastern Atlantic DPS

The ERA team concluded, and we agree, that the Eastern Atlantic DPS is at a ''high'' risk of extinction throughout all of its range, now and in the foreseeable future. The ERA team had serious concerns regarding the level of overutilization and lack of regulatory mechanisms in the Eastern Atlantic DPS. Although Spain and other EU countries have implemented new regulations aimed at protecting this species in the Atlantic, these management measures are lacking in the West African region where enforcement of existing measures is weak and IUU fishing is rampant. There is no evidence of this situation in western Africa changing in the foreseeable future, as resources are very limited. Thus, the ERA team concluded that overutilization by artisanal, industrial, and IUU fishing in this area is creating a DPS that is at or near a level of abundance and productivity that places its current and future persistence in question throughout its entire range. Likelihood points attributed to the categories for the current level of extinction risk are as follows: No or Very Low Risk (1/50), Low Risk (6/50), Moderate Risk (14/50), High Risk (18/50), and Very High Risk (11/50). Likelihood points attributed to the other categories for the level of extinction risk in the foreseeable future are as follows: Low Risk (7/50), Moderate Risk (14/50), High Risk (20/50), and Very High Risk (9/50). None of the team members placed a likelihood point in the ''No or very low risk'' category for the overall level of extinction risk in the foreseeable future, indicating their strong certainty that the DPS will be at some risk of extinction. Based on the likelihood point distributions, the team was less certain about the current risk of extinction for this DPS, with the moderate risk category separated from the high risk category by only four likelihood points. However, in the foreseeable future, the team expressed increased certainty that the DPS would be at a high risk of extinction with more likelihood points added to this category while the moderate risk category remained the same.

Indo-West Pacific DPS

The ERA team concluded, and we agree, that the Indo-West Pacific DPS is at a ''moderate'' risk of extinction throughout all of its range, now and in the foreseeable future. The ERA team was mainly concerned about the level of overutilization and limited regulatory mechanisms in the Indo-West Pacific DPS and concluded that the DPS is exhibiting a trajectory indicating that it is approaching a level of abundance and productivity that places its current and future persistence in question throughout its entire range. Given the inadequacy of current regulatory mechanisms, the reports of heavy fishing, increased industrialization, high at-vessel mortality rate, and the projected increase of commercial, artisanal, and IUU fishing, the team does not envision a reversal of demographic trends in the foreseeable future that would reduce its risk of extinction throughout all or a significant portion of its range. Likelihood points attributed to the categories for the current level of extinction risk are as follows: Low Risk (4/50), Moderate Risk (20/50), High Risk (17/50), and Very High Risk (9/50). None of the team members placed a likelihood point in the ''No or very low risk'' category for the overall level of extinction risk now or in the foreseeable future, indicating their strong certainty that the DPS is, and will continue to be, at some risk of extinction. Likelihood points attributed to the other categories for the level of extinction risk in the foreseeable future are as follows: Low Risk (3/50), Moderate Risk (19/50), High Risk (16/50), and Very High Risk (12/50). Based on the likelihood point distributions, the team was fairly certain that the DPS has a moderate to high risk of extinction. However, the difference of only three likelihood points separating these two risk categories indicates a level of uncertainty as to the severity of the current and future threats and demographic risks. In addition, three likelihood points were moved to the very high risk category in the foreseeable future. The team thought the DPS was at a moderate risk of extinction, but were concerned that the situation could actually be worse in the future.

Central Pacific DPS

The ERA team concluded, and we agree, that the Central Pacific DPS is at a ''no or very low'' risk of extinction throughout all of its range, now and in the foreseeable future. Although the ERA team had concerns regarding the threat of overutilization by commercial fisheries in combination with the scalloped hammerhead's tendency to school, they felt that the current abundance and productivity of this DPS, along with the number of suitable nursery grounds and effective management measures, provided ample protection from extinction for this DPS. Likelihood points attributed to the categories for the current level of extinction risk are as follows: No or Very Low Risk (24/50), Low Risk (19/50), and Moderate Risk (7/50). None of the team members placed a likelihood point in the ''High risk'' or ''Very High

Risk'' categories for the overall level of extinction risk now or in the foreseeable future, indicating their strong certainty that the DPS is not, nor will it be, at a high risk of extinction. Likelihood points attributed to the other categories for the level of extinction risk in the foreseeable future are as follows: No or Very Low Risk (27/50), Low Risk (17/50), and Moderate Risk (6/50). Based on the likelihood point distributions, the team was fairly certain that this DPS is at a no or very low risk of extinction now and in the foreseeable future.

Eastern Pacific DPS

The ERA team concluded, and we agree, that the Eastern Pacific DPS is at a ''high'' risk of extinction throughout all of its range, now and in the foreseeable future. The ERA team had strong concerns regarding the level of overutilization and limited regulatory mechanisms or enforcement of fishery regulations in the Eastern Pacific, and concluded that the DPS is at or near a level of abundance and productivity that places its current and future persistence in question throughout its entire range. Likewise, the present threats, which include heavy fishing, IUU fishing, and overutilization by industrial/commercial and artisanal fisheries, coupled with the behavioral and biological aspects that increase *S. lewini's* susceptibility and mortality to certain fishing gear, will only serve to exacerbate the demographic risks currently faced by the DPS in the foreseeable future. Likelihood points attributed to the current level of extinction risk categories are as follows: Low Risk (6/50), Moderate Risk (17/50), High Risk (21/50), and Very High Risk (5/50). None of the team members placed a likelihood point in the ''No or very low risk'' category for the overall level of extinction risk now or in the foreseeable future, indicating their strong certainty that the DPS is, and will continue to be, at some risk of extinction. Likelihood points attributed to the other categories for the level of extinction risk in the foreseeable future are as follows: Low Risk (4/50), Moderate Risk (15/50), High Risk (21/50), and Very High Risk (10/50). Based on the likelihood point distributions, the team was fairly certain that the DPS has a moderate to high risk of extinction, with the high risk category receiving more of the votes. In addition, five likelihood points were moved to the very high risk category in the foreseeable future, indicating increased concern for this DPS.

Efforts Being Made to Protect Scalloped Hammerhead Sharks

Section 4(b)(1)(A) of the ESA requires the Secretary of Commerce to take into account ''* * * efforts, if any, being made by any State or foreign nation, or any political subdivision of a State or foreign nation, to protect such species, whether by predator control, protection of habitat and food supply, or other conservation practices, within any area under its jurisdiction or on the high seas.'' The ESA therefore directs us to consider all conservation efforts being made to conserve the species. The joint USFWS and NOAA *Policy on Evaluation of Conservation Efforts When Making Listing Decisions* (''PECE Policy'', 68 FR 15100; March 28, 2003) further identifies criteria we use to determine whether formalized conservation efforts that have yet to be implemented or to show effectiveness contribute to making listing unnecessary, or to list a species as threatened rather than endangered. In determining whether a formalized conservation effort contributes to a basis for not listing a species, or for listing a species as threatened rather than endangered, we must evaluate whether the conservation effort improves the status of the species under the ESA. Two factors are key in that evaluation: (1) For those efforts yet to be implemented, the certainty that the conservation effort will be implemented and (2) for those efforts that have not yet demonstrated effectiveness, the certainty that the conservation effort will be effective. The following is a review of the major conservation efforts and an evaluation of whether these efforts are reducing or eliminating threats by having a positive conservation benefit and thus improving the status of the scalloped hammerhead shark DPSs.

U.S. Fishery Management: Amendment 5 to the Consolidated HMS FMP

On April 28, 2011, NMFS determined that the Northwest Atlantic and Gulf of Mexico scalloped hammerhead shark stock was overfished and experiencing overfishing (76 FR 23794; April 28, 2011). Under National Standard (NS) 1 of the MSA and implementing regulations (50 CFR 600.310), NMFS is required to ''prevent overfishing while achieving, on a continuing basis, the OY [optimum yield] from each fishery for the U.S. fishing industry.'' In order to accomplish this, NMFS must determine the MSY and specify status determination criteria to allow a determination of the status of the stock. In cases where NMFS has determined that a fishery is overfished, the MSA, Section 304, mandates that NMFS notify the appropriate Fishery Management Council and request that the Council take action. The Council must then take action within 2 years to end overfishing and rebuild the stock in the shortest time possible. The NMFS Atlantic HMS Management Division is responsible for managing scalloped hammerhead sharks, and is thus responsible for taking appropriate action to end overfishing and rebuild the fishery. Given this statutory mandate, there is a certainty that NMFS will implement conservation and management measures by 2013 that will provide for the rebuilding of the scalloped hammerhead shark stock. NMFS is currently in the process of finalizing Amendment 5 to the Consolidated HMS FMP (proposed on November 26, 2012, 77 FR 70552; public comment period closed February 12, 2013), which will prescribe management measures and implementing regulations to conserve the scalloped hammerhead shark NW Atlantic & GOM DPS.

The second criterion of the PECE policy is the evaluation that the conservation effort will be effective. The specific conservation effort that is trying to be achieved is the rebuilding of the Northwest Atlantic and Gulf of Mexico scalloped hammerhead shark stock. The conservation effort is achieved when the current biomass (B) levels of the stock are equal to B_{MSY}. B_{MSY} is the level of stock abundance at which harvesting the resource can be sustained on a continual basis at the level necessary to support MSY. Stocks are considered healthy when F (fishing caused mortality) is less than or equal to 0.75 F_{MSY} and B is greater than or equal to B_{OY} (B_{OY} = approximately 1.25 to 1.30 B_{MSY}; the biomass level necessary to produce OY on a continuing basis). Specifically, NMFS will establish annual catch limits and accountability measures for the scalloped hammerhead shark stock to allow for rebuilding of the stock. With fishery rebuilding plans, there is an explicit time frame for achieving this conservation effort, which will be stated in the Amendment to the FMP. Usually, rebuilding targets are set at 10 years unless the biology of the stock of fish, other environmental conditions, or management measures under an international agreement in which the United States participates, dictate otherwise. Then the specified time period for rebuilding may be adjusted upward by one mean generation time. The rebuilding plans are based on quantifiable, scientifically valid parameters and the progress of the

stock is monitored and reported on as stock assessments are conducted. Although Amendment 5 has not yet been finalized, examination of previous rebuilding plans for Atlantic coastal shark species may provide insight into the effectiveness of these regulatory measures.

Section 304(e)(7) of the Magnuson-Stevens Act requires that the Secretary review rebuilding progress at routine intervals that may not exceed 2 years, and thus every year NMFS tracks the biomass trends for overfished stocks to monitor this rebuilding progress. Overall, the total number of stocks that have been rebuilt under a rebuilding plan since 2001 is 26 (approximately 11 percent of the total number of managed stocks, and 34 percent of the stocks that have/had rebuilding plans). Of the 21 stocks managed by the 2006 Consolidated HMS FMP, around half are currently under a rebuilding plan. Two HMS stocks have rebuilt since being under a rebuilding plan: Atlantic swordfish, which was rebuilt in year 9 of a 10-year plan, and the Atlantic blacktip shark, which is thought to have been rebuilt in year 5 of a 39-year plan (however, this stock may have never been overfished).

The status of the sandbar shark stock may provide a better comparison to the potential success rate of the scalloped hammerhead shark rebuilding plan. The sandbar shark used to be managed as part of the LCS complex; however, enough data were available to conduct a separate stock assessment of the species. In 2006, the results of the sandbar shark stock assessment showed that the stock was overfished with overfishing occurring. Using the available scientific information, NMFS published Amendment 2 to the 2006 Consolidated HMS FMP, establishing the rebuilding plan for the sandbar shark. Management measures in the implementing regulations included separating the sandbar shark from the LCS complex and setting specific quotas and retention limits for the species that would allow it to rebuild. Specifically, NMFS allowed sandbar retention only by vessels with shark research permits, and the limits depended upon research objectives. The success of this rebuilding plan can be seen in the latest SouthEast Data, Assessment, and Review (SEDAR 21) of the sandbar shark stock (finalized in 2011), which determined that the sandbar shark stock was still overfished but no longer experiencing overfishing. In addition, it was also determined that the current total allowable catch (TAC) for the fishery could result in a greater than 70 percent probability of rebuilding by the current rebuilding date of 2070. Similar to the sandbar shark, NMFS is working to develop a rebuilding plan that will set specific quota and retention limits for scalloped hammerhead sharks and allow for the recovery of these sharks in the Northwest Atlantic and Gulf of Mexico. Based on the criteria in the PECE policy, in our judgment the Amendment 5 to the Consolidated HMS FMP is a conservation effort with high certainty of implementation and is highly likely to be sufficiently effective to substantially reduce the overutilization of the NW Atlantic & GOM scalloped hammerhead shark DPS. Overutilization of this DPS by commercial and recreational fisheries was identified as a primary threat presenting a moderate risk of extinction to the DPS currently, but was expected to decrease in risk severity in the foreseeable future. We anticipate that the foregoing conservation measures will benefit the status of the species in the foreseeable future, thereby further decreasing its extinction risk from the threat of overutilization identified by the ERA team.

Shark Fin Bans

The concern regarding the practice of finning and its effect on global shark populations has been growing both domestically and internationally. In the United States, California, Oregon, Washington, and Hawaii have already passed legislation banning the sale, possession, and distribution of shark fins. The support for this legislation from the public, as well as conservation groups, has prompted many other states to follow suit, with proposals for similar bills. Likewise, in Canada, Bill C–380 was introduced in December of 2011, and would prohibit the import or attempt to import shark fins that are not attached to the rest of the shark carcass into Canada.

The push to stop shark finning and curb the trade of shark fins is also evident overseas and most surprisingly in Asian countries, where the demand for shark fin soup is highest. Taiwan, the third top exporter of shark fins to Hong Kong in 2008, banned the practice of shark finning at sea in 2012. Likewise, many hotels in Taiwan, such as the W Taipei, the Westin Taipei, and the Silks Palace at National Palace Museum, also vowed to stop serving shark fin dishes as part of their menus. In November of 2011, the Chinese restaurant chain South Beauty removed shark fin soup from its menus, and in 2012, the luxury Shangri-La Hotel chain joined this effort, banning shark fin from its 72 hotels, most of which are found in Asia. Effective January 1, 2012, the Peninsula Hotel chain stopped serving shark fin and related products. This ban covers the Chinese restaurant and banqueting facilities at The Peninsula hotels in Hong Kong, Shanghai, Beijing, Tokyo, Bangkok, and Chicago. Many supermarket chains in Asia also vowed to halt the sale of shark fin products. In 2011, ColdStorage, a chain with several outlets in Singapore, banned the sale of shark fin from its stores, and in 2012, the Singapore supermarket chains FairPrice and Carrefour stated they would also stop selling shark fin in outlets in the city-state. Many of these bans have just recently been implemented, and thus their effect on reducing the threat of *S. lewini* overutilization is unknown.

While there seems to be a growing trend to prohibit and discourage shark finning domestically and internationally, it is difficult to predict at this time whether the trend will be effective in reducing the threat of IUU fishing to any particular DPS. We do not find these to be conservation measures that we consider effective in reducing current threats to the any of the DPSs as we evaluate whether listing is warranted.

Convention on International Trade in Endangered Species of Wild Fauna and Flora

CITES is an international agreement between governments that regulates international trade in wild animals and plants. It encourages a proactive approach and the species covered by CITES are listed in appendices according to the degree of endangerment and the level of protection provided. Appendix I includes species threatened with extinction; trade in specimens of these species is permitted only in exceptional circumstances. Appendix II includes species not necessarily threatened with extinction, but for which trade must be controlled to avoid exploitation rates incompatible with species survival. Appendix III contains species that are protected in at least one country, which has asked other CITES Parties for assistance in controlling the trade.

In 2012, *S. lewini* was submitted for inclusion on CITES Appendix III by Costa Rica, and is now effectively listed in the appendix. An Appendix III listing allows international trade of the species, but provides a means of gathering trade data and other relevant information. For example, the export of *S. lewini* specimens from Costa Rica requires a CITES export permit issued by the Costa Rica CITES Management Authority. For the export of *S. lewini* specimens from any other country, a CITES certificate of

origin by the Management Authority of that country is required. This conservation effort will allow Costa Rica to gain better international cooperation in controlling trade of *S. lewini* both into and out of the country. This type of tracking information will also provide previously unavailable data on the origin of *S. lewini* specimens, including fins, currently being traded in the global market and allow for a better determination of the degree of exploitation and use of this species by domestic and foreign fishing fleets. Although this CITES listing will likely provide us with better data in the future to assess the status of DPSs, it is not a conservation measure that we consider effective in reducing current threats to the any of the DPSs as we evaluate whether listing is warranted.

Other Conservation Efforts

There are many other smaller national and international organizations with shark-focused goals that include advocating the conservation of sharks through education and campaign programs and conducting shark research to fill data gaps regarding the status of shark species. These organizations include: the Pew Environment Group, Oceana, Ocean Conservancy, Shark Trust, Bite-Back, Shark Project, Pelagic Shark Research Foundation, Shark Research Institute, and Shark Savers. More information on the specifics of these programs and groups can be found on their Web sites. All of these conservation efforts and non-regulatory mechanisms are beneficial to the persistence of the scalloped hammerhead shark. The implementation of many of these efforts, especially the shark research programs as well as the CITES Appendix III listing, will help to fill current data gaps in *S. lewini* abundance and utilization records. However, it is too soon to tell whether the collective conservation efforts of non-governmental organizations targeting finning practices and promoting public awareness of declines in shark populations will be effective in reducing the threats, particularly those related to overutilization of the scalloped hammerhead DPSs. Much of the data on shark catches and exports since implementation of these conservation efforts is not yet available.

Proposed Determinations

Section 4(b)(1) of the ESA requires that NMFS make listing determinations based solely on the best scientific and commercial data available after conducting a review of the status of the species and taking into account those efforts, if any, being made by any state or foreign nation, or political subdivisions thereof, to protect and conserve the species. We have reviewed the best available scientific and commercial information including the petition, the status review report (Miller *et al.,* 2013), and other published and unpublished information, and we have consulted with species experts and individuals familiar with scalloped hammerhead sharks.

For the reasons stated above, and as summarized below, we conclude that: (1) Scalloped hammerhead sharks in the NW Atlantic & GOM, Central & SW Atlantic, Eastern Atlantic, Indo-West Pacific, Central Pacific, and Eastern Pacific meet the discreteness and significance criteria for DPSs; (2) the Eastern Atlantic and Eastern Pacific scalloped hammerhead shark DPSs are in danger of extinction throughout their ranges; (3) the Central & SW Atlantic and Indo-West Pacific scalloped hammerhead shark DPSs are likely to become endangered throughout their ranges in the foreseeable future; and (4) the NW Atlantic & GOM and Central Pacific scalloped hammerhead shark DPs are not in danger of extinction or likely to become so throughout all of their ranges in the foreseeable future.

Scalloped hammerhead sharks occurring in the NW Atlantic & GOM are discrete and significant from other members of their species based on the following: (1) Genetic differences between this population and those scalloped hammerhead sharks inhabiting waters of the Pacific, Indian, and eastern Atlantic oceans; (2) tagging studies that show limited distance movements, with no tagged sharks observed in Central America or Brazil, supporting the conclusion that the NW Atlantic & GOM population is isolated from other populations; (3) significant U.S. fishery management measures for this population that separate it from scalloped hammerheads found in the Central & SW Atlantic (with the exception of those in the U.S. EEZ Caribbean), with differences in control of *S. lewini* exploitation and regulatory mechanisms of significance across these international boundaries; and (4) evidence that a loss of this segment would result in a significant gap in the range of the taxon (from New Jersey to Florida and throughout the GOM), with tagging and genetic studies that suggest the segment would unlikely be rapidly repopulated through immigration.

Scalloped hammerhead sharks occurring in the Central & SW Atlantic are discrete and significant from other members of their species based on the following: (1) Genetic differences between this population and those scalloped hammerhead sharks inhabiting waters of the Pacific, Indian, and eastern Atlantic oceans; (2) tagging studies that suggest limited distance migrations along coastlines, continental margins, and submarine features with no observed mixing between the Central & SW Atlantic population and the NW Atlantic & GOM population, supporting the conclusion of isolation from other populations; (3) fishery management measures that are lacking in this DPS compared to NW Atlantic & GOM DPS (with the exception of U.S. EEZ Caribbean), with differences in control *S. lewini* exploitation and regulatory mechanisms of significance across these international boundaries; and (4) evidence that a loss of this segment would result in a significant gap in the range of the taxon (from Caribbean to Uruguay), with oceanographic conditions that would act as barriers to re-colonization, and tagging and genetic studies that suggest the segment would unlikely be rapidly repopulated through immigration.

Scalloped hammerhead sharks occurring in the Eastern Atlantic are discrete and significant from other members of their species based on the following: (1) Genetic differences between this population and those scalloped hammerhead sharks inhabiting waters of the Pacific, Indian, and western Atlantic oceans; (2) tagging studies that suggest limited distance migrations along coastlines, continental margins, and submarine features, with genetic studies that show migration around the southern tip of Africa is rare (i.e., no mixing with those sharks found in the Indian Ocean), supporting the conclusion of isolation from other populations; and (4) evidence that loss of this segment would result in a significant gap in the range of the taxon (from Mediterranean Sea to Namibia), with oceanographic conditions that would act as barriers to re-colonization, and tagging and genetic studies that suggest the segment would unlikely be rapidly repopulated through immigration.

Scalloped hammerhead sharks occurring in the Indo-West Pacific are discrete from other members of their species based on the following: (1) Genetic differences between this population and those scalloped hammerhead sharks inhabiting waters of the Eastern Pacific and Atlantic oceans; (2) tagging and genetic studies that show limited distance migrations and support isolation from other populations, but suggest males mix readily along coastlines and continental margins in this DPS due to the high connectivity of

habitat; (3) fishery management measures that are lacking in this DPS compared to those found in the Central Pacific DPS range, with differences in control of *S. lewini* exploitation and regulatory mechanisms of significance across international boundaries; and (4) evidence that loss of this segment would result in a significant gap in the range of the taxon (from South Africa to Japan and south to Australia and New Caledonia and neighboring Island countries), with oceanographic conditions that would act as barriers to re-colonization, and tagging and genetic studies that suggest the segment would unlikely be rapidly repopulated through immigration.

Scalloped hammerhead sharks occurring in the Central Pacific are discrete from other members of their species based on the following: (1) Genetic differences between this population and those scalloped hammerhead sharks inhabiting waters of the Eastern Pacific and Atlantic oceans; (2) tagging studies that show limited distance migrations, with adults remaining ''coastal'' within the archipelago, and separated from other populations by bathymetric barriers, supporting the conclusion of isolation from other populations; (3) significant U.S. fishery management measures for this DPS that separate it from the Indo-West Pacific DPS, with differences in control of *S. lewini* exploitation and regulatory mechanisms of significance across international boundaries; and (4) evidence that loss of this segment would result in a significant gap in the range of the taxon (from Kure Atoll to Johnston Atoll, including the Hawaiian Archipelago) and valuable and productive nursery grounds, with oceanographic conditions that would act as barriers to re-colonization, and tagging and genetic studies that suggest this segment would unlikely be rapidly repopulated through immigration.

Scalloped hammerhead sharks occurring in the Eastern Pacific are discrete from other members of their species based on the following: (1) Genetic differences between this population and those scalloped hammerhead sharks inhabiting waters of the Indo-West Pacific, Central Pacific, and Atlantic oceans; (2) tagging studies that suggest wide movements around island and occasional long-distance dispersals between neighboring islands with similar oceanographic conditions, but isolation from other DPSs by bathymetric barriers and oceanographic conditions, supporting the conclusion of isolation from other populations; and (4) evidence that loss of this segment would result in a significant gap in the range of the taxon (from southern CA, USA to Peru), with oceanographic conditions that would act as barriers to re-colonization, and tagging and genetic studies that suggest the segment would unlikely be rapidly repopulated through immigration.

The ESA does not define the terms ''significant portion of its range'' (SPOIR) or ''foreseeable future.'' With regard to SPOIR, we (NMFS and U.S. Fish and Wildlife Service, or, the Services) have proposed a ''Draft Policy on Interpretation of the Phrase 'Significant Portion of Its Range' in the Endangered Species Act's Definitions of 'Endangered Species' and 'Threatened Species'" (76 FR 76987; December 9, 2011), which is consistent with our past practice as well as our understanding of the statutory framework and language. While the Draft Policy remains in draft form, the Services are to consider the interpretations and principles contained in the Draft Policy as non-binding guidance in making individual listing determinations, while taking into account the unique circumstances of the species under consideration.

The Draft Policy provides that: (1) If a species is found to be endangered or threatened in only a significant portion of its range, the entire species is listed as endangered or threatened, respectively, and the Act's protections apply across the species' entire range; (2) a portion of the range of a species is ''significant'' if its contribution to the viability of the species is so important that, without that portion, the species would be in danger of extinction; (3) the range of a species is considered to be the general geographical area within which that species can be found at the time FWS or NMFS makes any particular status determination; and (4) if the species is not endangered or threatened throughout all of its range, but it is endangered or threatened within a significant portion of its range, and the population in that significant portion is a valid DPS, we will list the DPS rather than the entire taxonomic species or subspecies.

Given that the scalloped hammerhead shark is a highly mobile species, with very few restrictions governing its movements within each DPS, we did not find any evidence to suggest that a portion of any single DPS' range had increased importance over another with respect to the species' survival within each respective DPS. The ERA team initially considered the islands in the Central Pacific as a potential SPOIR, given their numerous nursery grounds and likelihood as a population source for the region. However, upon further review, the ERA team found that this area qualified as a DPS and analyzed it as such. In addition, the available data did not indicate any portion of any DPS range as being more significant than another. Potentially important aspects of a DPS range, such as identified nursery grounds or ''hot spots'' of aggregations, were represented elsewhere in the range, suggesting that if the population in a specific nursery ground or ''hot spot'' disappeared, the DPS would not be in danger of extinction throughout its range. There was no evidence of any DPS being limited to a specific nursery ground or schooling location. In fact, Duncan *et al.* (2006) provided mtDNA data that argued against strong natal homing behavior by the species, and instead suggested that the habitat characteristics of the nursery area were more important than the location. Since available nursery habitat was not identified as a limiting factor in any of the DPSs, we did not consider this as a significant portion of range. Thus, when making our determinations, we considered the status of each DPS throughout its entire range as no SPOIRs could be identified.

With respect to the term ''foreseeable future,'' we accepted the ERA team's definition and rationale of 50 years as reasonable for the reliable prediction of threats to the biological status of the species. That rationale was provided in detail above.

As discussed, we have independently reviewed and evaluated the best available scientific and commercial information related to the status of each DPS, including the demographic risks and trends and the multiple threats related to the factors set forth in the ESA Section 4(a)(1)(A)–(E). As we explained, no portion of any DPS's range is considered significant and we therefore have determined that no DPS is threatened or endangered in a significant portion of its range. Our determinations set forth above and summarized below are thus based on the status of each DPS across its entire range. Based on our evaluation of the status of each DPS and the threats to its persistence we predicted the likelihood that each DPS is in danger of extinction throughout all of its range now and in the foreseeable future. We considered each of the statutory factors to determine whether it presented an extinction risk to each DPS on its own. We also considered the combination of those factors to determine whether they collectively contributed to the extinction of each DPS. As required by the ESA, Section 4(b)(1)(a), we also took into account efforts to protect scalloped hammerhead sharks by states, foreign nations and others and evaluated

whether those efforts provide a conservation benefit to each DPS and reduced threats to the extent that a DPS did not warrant listing or could be listed as threatened rather than endangered. Our conclusions and proposed listing determinations are based on a synthesis and integration of the foregoing information, factors and considerations.

Below are the summaries of our proposed determinations:

We have determined that the Eastern Atlantic DPS of scalloped hammerhead sharks is currently in danger of extinction throughout all of its range. Factors supporting this conclusion include overutilization, inadequacy of existing regulatory mechanisms and other natural or manmade factors, specifically: (1) Low productivity rates; (2) high susceptibility to overfishing, especially given its schooling behavior; (3) significant historical removals of sharks, including scalloped hammerheads, by artisanal and industrial fisheries, with directed shark fisheries still in operation and heavy fishing pressure despite evidence of species' extirpations and declines of large hammerheads; (4) high at-vessel mortality rate associated with incidental capture in fisheries (resulting in further reduction of population productivity and abundance); (5) popularity of the species in the shark fin trade; and (6) inadequate regulatory mechanisms along the coast of West Africa, with severe enforcement issues leading to heavy IUU fishing. Therefore, we propose to list the Eastern Atlantic DPS of scalloped hammerhead sharks as endangered.

We have determined that the Eastern Pacific DPS of scalloped hammerhead sharks is also currently in danger of extinction throughout all of its range. Factors supporting this conclusion include overutilization, inadequacy of existing regulatory mechanisms and other natural or manmade factors, specifically: (1) Reduced abundance, declining population trends and catch, and evidence of size truncation; (2) low productivity rates; (2) high susceptibility to overfishing, especially given its schooling behavior, with artisanal fisheries targeting juveniles of the species in inshore and nursery areas; (3) high at-vessel mortality rate associated with incidental capture in fisheries (resulting in further reduction of population productivity and abundance); (4) popularity of the species in the shark fin trade and importance in Mexican artisanal fisheries; and (5) limited regulatory mechanisms and weak enforcement in many areas, leading to IUU fishing of the species, especially in protected waters. Therefore, we propose to list the Eastern Pacific DPS of scalloped hammerhead sharks as endangered.

We have determined that the Central & SW Atlantic DPS of scalloped hammerhead sharks is not presently in danger of extinction, but likely to become so in the foreseeable future throughout all of its range. Factors supporting a conclusion that this DPS is not presently in danger of extinction include: (1) Low productivity rates but moderate rebound potential to pelagic longline fisheries common in this DPS; (2) ICCAT recommendations slated for implementation (or already implemented) by Contracting Parties that offer protection for this species from ICCAT fishing vessels; (3) regulations that limit the extension of pelagic gillnets and trawls, shark fin bans, and prohibitions on shark fishing or the retention of scalloped hammerhead sharks; and (4) evidence that sharks are still present in significant enough numbers to be caught by commercial and artisanal fisheries. Factors supporting a conclusion that the DPS is likely to become in danger of extinction in the foreseeable future include overutilization, inadequacy of existing regulatory mechanisms and other natural or manmade factors, specifically: (1) Decreasing catch trends suggesting population decline, (2) high susceptibility to overfishing, especially given its schooling behavior, with artisanal fisheries catching large numbers of juveniles in inshore and nursery areas; (3) high at-vessel mortality rate associated with incidental capture in fisheries (resulting in further reduction of population productivity and abundance); (4) popularity of the species in the shark fin trade; and (5) limited regulatory mechanisms and/or weak enforcement in some areas, leading to IUU fishing of the species. Therefore, we propose to list the Central & SW Atlantic DPS of scalloped hammerhead sharks as threatened.

We have determined that the Indo-West Pacific DPS of scalloped hammerhead sharks is not presently in danger of extinction, but likely to become so in the foreseeable future throughout all of its range. Factors supporting a conclusion that this DPS is not presently in danger of extinction include: (1) Relatively high reported catches of the species off the coasts of South Africa and Queensland, Australia; (2) still observed throughout the entire range of this DPS with the overall population size uncertain given the expansive range of this DPS; and (3) current regulations that prevent the waste of shark parts and discourage finning in this region, with the number of shark sanctuaries on the rise in the Western Pacific. Factors supporting a conclusion that the DPS is likely to become in danger of extinction in the foreseeable future include overutilization, inadequacy of existing regulatory mechanisms and other natural or manmade factors, specifically: (1) Decreases in CPUE of sharks off the coasts of South Africa and Australia and in longline catch in Papua New Guinea and Indonesian waters, suggesting localized population declines, (2) high susceptibility to overfishing, especially given its schooling behavior, in artisanal fisheries and industrial/commercial fisheries; (3) high at-vessel mortality rate associated with incidental capture in fisheries (resulting in further reduction of population productivity and abundance); (4) popularity of the species in the shark fin trade; and (5) inadequate regulatory mechanisms and/or weak enforcement of current regulations in many areas, resulting in frequent reports of IUU fishing of the species. Therefore, we propose to list the Indo-West Pacific DPS of scalloped hammerhead sharks as threatened.

We conclude that the NW Atlantic & GOM DPS of scalloped hammerhead sharks is not presently in danger of extinction, nor is it likely to become so in the foreseeable future throughout all of its range. Factors supporting this conclusion include: (1) Abundance numbers for this DPS that are lower than historical levels but seem to have been constant over the past few years, with a high probability of population recovery under recent catch levels; (2) significant fishery management measures that are in place, including both state and Federal regulations, with scalloped hammerhead-specific sustainability, conservation, and rebuilding goals; (3) extensive EFH for the species that has been designated along the range of this DPS, with no evidence of habitat loss or destruction; and (4) low productivity rates for the species but moderate rebound potential to pelagic longline fisheries within the range of this DPS. We determined that the comprehensive science-based management of this DPS and enforceable and effective regulatory structure as discussed previously in this proposed rule significantly minimize this DPS' extinction risk from threats of overutilization and IUU fishing to the point where we do not find this DPS in danger of extinction now or in the foreseeable future. Under current fishery management, the DPS has a high probability of rebuilding within 50 years, and considering formalized

conservation efforts, such as Amendment 5 to the HMS FMP and implementing regulations, we find that these regulatory mechanisms are likely to further reduce the significant threats to this DPS (primarily overexploitation by commercial and recreational fisheries, exacerbated by the species' high at-vessel fishing mortality) and benefit the conservation status of the DPS. Therefore, we conclude that listing the NW Atlantic & GOM scalloped hammerhead shark DPS as threatened or endangered under the ESA is not warranted at this time.

We also conclude that the Central Pacific DPS of scalloped hammerhead sharks is not presently in danger of extinction, nor is it likely to become so in the foreseeable future throughout all of its range. Factors supporting this conclusion include: (1) Abundance numbers for this DPS that are perceived to be high; (2) ample productive nursery grounds that are present in the range of this DPS, with no evidence of habitat loss or destruction; (3) low productivity rates for the species but data that show it is rarely caught in Hawaiian-based fisheries; and (4) significant fishery management measures that are in place, including both state and Federal regulations, that protect the species from extinction. We determined that the high population abundance of this DPS and effective existing fishery management measures and regulatory structure, reflected in the rare catch of this DPS in fisheries operating within its range, minimized the threat of overutilization by commercial fisheries to the point where this DPS is not currently at risk of extinction. In addition, we find that regulatory mechanisms will likely only increase in their strength and effectiveness in minimizing the extinction risk of this DPS in the next 50 years, making it unlikely that the threat of overutilization will be a significant risk to this DPS' continued existence in the foreseeable future. Therefore, we conclude that listing the Central Pacific scalloped hammerhead shark DPS as threatened or endangered under the ESA is not warranted at this time.

Effects of Listing

Conservation measures provided for species listed as endangered or threatened under the ESA include recovery plans and actions (16 U.S.C. 1536(f)); concurrent designation of critical habitat if prudent and determinable (16 U.S.C. 1533(a)(3)(A)); Federal agency requirements to consult with NMFS and to ensure its actions do not jeopardize the species or result in adverse modification or destruction of critical habitat should it be designated (16 U.S.C. 1536); and prohibitions on taking (16 U.S.C. 1538). Recognition of the species' plight through listing promotes conservation actions by Federal and state agencies, foreign entities, private groups, and individuals. Should the proposed listings be made final, a recovery plan or plans may be developed, unless such plan would not promote the conservation of the species.

Identifying Section 7 Consultation Requirements

Section 7(a)(2) (16 U.S.C. 1536(a)(2)) of the ESA and NMFS/FWS regulations require Federal agencies to confer with us on actions likely to jeopardize the continued existence of species proposed for listing, or that result in the destruction or adverse modification of proposed critical habitat. If a proposed species is ultimately listed, Federal agencies must consult on any action they authorize, fund, or carry out if those actions may affect the listed species or its critical habitat and ensure that such actions do not jeopardize the species or result in adverse modification or destruction of critical habitat should it be designated. Examples of Federal actions that may affect scalloped hammerhead shark DPSs include, but are not limited to: alternative energy projects, discharge of pollution from point sources, non-point source pollution, contaminated waste and plastic disposal, dredging, pile-driving, water quality standards, vessel traffic, aquaculture facilities, military activities, and fisheries management practices.

Critical Habitat

Critical habitat is defined in section 3 of the ESA (16 U.S.C. 1532(3)) as: (1) The specific areas within the geographical area occupied by a species, at the time it is listed in accordance with the ESA, on which are found those physical or biological features (a) essential to the conservation of the species and (b) that may require special management considerations or protection; and (2) specific areas outside the geographical area occupied by a species at the time it is listed upon a determination that such areas are essential for the conservation of the species. ''Conservation'' means the use of all methods and procedures needed to bring the species to the point at which listing under the ESA is no longer necessary. Section 4(a)(3)(a) of the ESA (16 U.S.C. 1533(a)(3)(A)) requires that, to the extent prudent and determinable, critical habitat be designated concurrently with the listing of a species. Designations of critical habitat must be based on the best scientific data available and must take into consideration the economic, national security, and other relevant impacts of specifying any particular area as critical habitat. If we determine that it is prudent and determinable, we will publish a proposed designation of critical habitat for scalloped hammerhead sharks in a separate rule. Public input on features and areas that may meet the definition of critical habitat for the Central & SW Atlantic, Indo-West Pacific, and Eastern Pacific DPS is invited. These DPSs are the only DPSs proposed for listing that occur in U.S. waters or its territories.

Take Prohibitions

Because we are proposing to list the Eastern Pacific and Eastern Atlantic DPSs as endangered, all of the take prohibitions of section 9(a)(1) of the ESA (16 U.S.C. 1538(a)(1)) will apply to those particular species if they become listed as endangered. These include prohibitions against importing, exporting, engaging in foreign or interstate commerce, or ''taking'' of the species. ''Take'' is defined under the ESA as ''to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or attempt to engage in any such conduct.'' These prohibitions apply to all persons, organizations and entities subject to the jurisdiction of the United States, including in the United States, its territorial sea, or on the high seas.

In the case of threatened species, ESA section 4(d) requires the Secretary to issue regulations deemed necessary and appropriate for the conservation of the species. We have flexibility under section 4(d) to tailor protective regulations based on the needs of and threats to the species. The section 4(d) protective regulations may prohibit, with respect to threatened species, some or all of the acts which section 9(a) of the ESA prohibits with respect to endangered species. We will evaluate protective regulations pursuant to section 4(d) for the threatened scalloped hammerhead shark DPSs and propose any considered necessary and advisable for conservation of these species in a future rulemaking. In order to inform our consideration of appropriate protective regulations for these DPSs, we seek information from the public on the threats to the Central & SW Atlantic DPS and the Indo-West Pacific DPS and possible measures for their conservation.

Identification of Those Activities That Would Constitute a Violation of Section 9 of the ESA

On July 1, 1994, NMFS and FWS published a policy (59 FR 34272) that

requires us to identify, to the maximum extent practicable at the time a species is listed, those activities that would or would not constitute a violation of section 9 of the ESA. The intent of this policy is to increase public awareness of the effect of a listing on proposed and ongoing activities within a species' range. We will identify, to the extent known at the time of the final rule, specific activities that will not be considered likely to result in violation of section 9, as well as activities that will be considered likely to result in violation. Based on currently available information, we conclude that the following types of activities are those that may be most likely to violate the section 9 prohibitions against ''take'' of the scalloped hammerhead shark Eastern Atlantic and Eastern Pacific DPSs include, the following: (1) Importation of fins or any part of a scalloped hammerhead shark; (2) exportation of fins or any part of a scalloped hammerhead shark; (3) take of fins or any part of a scalloped hammerhead shark, including fishing for, capturing, handling, or possessing scalloped hammerhead sharks or fins; (4) sale of fins or any part of a scalloped hammerhead shark; (5) delivery of fins or any part of a scalloped hammerhead shark; and (6) any activities that may impact the water column attributes in scalloped hammerhead nursery grounds (e.g. development and habitat alterations, point and non-point source discharge of persistent contaminants, toxic waste and other pollutant disposal). We emphasize that whether a violation results from a particular activity is entirely dependent upon the facts and circumstances of each incident. The mere fact that an activity may fall within one of these categories does not mean that the specific activity will cause a violation; due to such factors as location and scope, specific actions may not result in direct or indirect adverse effects on the species. Further, an activity not listed may in fact result in a violation.

Role of Peer Review

The intent of the peer review policy is to ensure that listings are based on the best scientific and commercial data available. In December 2004, the Office of Management and Budget (OMB) issued a Final Information Quality Bulletin for Peer Review establishing minimum peer review standards, a transparent process for public disclosure of peer review planning, and opportunities for public participation. The OMB Bulletin, implemented under the Information Quality Act (Pub. L. 106–554), is intended to enhance the quality and credibility of the Federal government's scientific information, and applies to influential or highly influential scientific information disseminated on or after June 16, 2005. To satisfy our requirements under the OMB Bulletin, we obtained independent peer review of the status review report. Independent specialists were selected from the academic and scientific community for this review. All peer reviewer comments were addressed prior to dissemination of the final status review report and publication of this proposed rule.

On July 1, 1994, the NMFS and USFWS published a series of policies regarding listings under the ESA, including a policy for peer review of scientific data (59 FR 34270). The intent of the peer review policy is to ensure that listings are based on the best scientific and commercial data available. Prior to a final listing, NMFS will solicit the expert opinions of three qualified specialists selected from the academic and scientific community, Federal and state agencies, and the private sector on listing recommendations to ensure the best biological and commercial information is being used in the decision-making process, as well as to ensure that reviews by recognized experts are incorporated into the review process of rulemakings developed in accordance with the requirements of the ESA.

Public Comments Solicited on Listing

To ensure that the final action resulting from this proposal will be as accurate and effective as possible, we solicit comments and suggestions from the public, other governmental agencies, the scientific community, industry, environmental groups, and any other interested parties. Comments are encouraged on this proposal (See **DATES** and **ADDRESSES**). Specifically, we are interested in information regarding: (1) The proposed scalloped hammerhead DPS delineations; (2) the population structure of scalloped hammerhead sharks; (3) habitat within the range of the proposed for listing DPSs that was present in the past, but may have been lost over time; (4) biological or other relevant data concerning any threats to the scalloped hammerhead shark DPSs we propose for listing; (5) the range, distribution, and abundance of these scalloped hammerhead shark DPSs; (6) current or planned activities within the range of the scalloped hammerhead shark DPSs we propose for listing and their possible impact on these DPSs; (7) recent observations or sampling of the scalloped hammerhead shark DPSs we propose for listing; and (8) efforts being made to protect the scalloped hammerhead shark DPSs we propose to list. We are also specifically interested in information regarding the Indo-West Pacific DPS, mainly the population structure, range, distribution, and recent observations or sampling of scalloped hammerhead sharks around the Western Pacific Islands.

Public Comments Solicited on Critical Habitat

We request quantitative evaluations describing the quality and extent of habitats for the Central & SW Atlantic, Eastern Pacific, and Indo-West Pacific DPSs, as well as information on areas that may qualify as critical habitat for these proposed DPSs. Specific areas that include the physical and biological features essential to the conservation of these DPSs, where such features may require special management considerations or protection, should be identified. Essential features may include, but are not limited to, features specific to individual species' ranges, habitats and life history characteristics within the following general categories of habitat features: (1) Space for individual growth and for normal behavior; (2) food, water, air, light, minerals, or other nutritional or physiological requirements; (3) cover or shelter; (4) sites for reproduction and development of offspring; and (5) habitats that are protected from disturbance or are representative of the historical, geographical, and ecological distributions of the species (50 CFR 424.12(b)). Areas outside the occupied geographical area should also be identified, if such areas themselves are essential to the conservation of the species. ESA implementing regulations at 50 CFR 424.12(h) specify that critical habitat shall not be designated within foreign countries or in other areas outside of U.S. jurisdiction. Therefore, we request information only on potential areas of critical habitat within waters under U.S. jurisdiction.

Section 4(b)(2) of the ESA requires the Secretary to consider the ''economic impact, impact on national security, and any other relevant impact'' of designating a particular area as critical habitat. Section 4(b)(2) also authorizes the Secretary to exclude from a critical habitat designation those particular areas where the Secretary finds that the benefits of exclusion outweigh the benefits of designation, unless excluding that area will result in extinction of the species. For features and areas potentially qualifying as critical habitat, we also request information describing: (1) Activities or other threats to the essential features or

activities that could be affected by designating them as critical habitat; and (2) the positive and negative economic, national security and other relevant impacts, including benefits to the recovery of the species, likely to result if these areas are designated as critical habitat. We seek information regarding the conservation benefits of designating areas within waters under U.S. jurisdiction as critical habitat. In keeping with the guidance provided by OMB (2000; 2003), we seek information that would allow the monetization of these effects to the extent possible, as well as information on qualitative impacts to economic values.

Data reviewed may include, but are not limited to: (1) Scientific or commercial publications; (2) administrative reports, maps or other graphic materials; (3) information received from experts; and (4) comments from interested parties. Comments and data particularly are sought concerning: (1) Maps and specific information describing the amount, distribution, and use type (e.g., foraging or migration) by the proposed scalloped hammerhead shark DPSs, as well as any additional information on occupied and unoccupied habitat areas; (2) the reasons why any habitat should or should not be determined to be critical habitat as provided by sections 3(5)(A) and 4(b)(2) of the ESA; (3) information regarding the benefits of designating particular areas as critical habitat; (4) current or planned activities in the areas that might be proposed for designation and their possible impacts; (5) any foreseeable economic or other potential impacts resulting from designation, and in particular, any impacts on small entities; (6) whether specific unoccupied areas may be essential to provide additional habitat areas for the conservation of the proposed DPSs; and (7) potential peer reviewers for a proposed critical habitat designation, including persons with biological and economic expertise relevant to the species, region, and designation of critical habitat. We seek information regarding critical habitat for the proposed scalloped hammerhead shark DPSs as soon as possible, but no later than July 5, 2013.

Public Hearings

If requested by the public by May 20, 2013, hearings will be held regarding the proposed scalloped hammerhead shark DPSs. If hearings are requested, details regarding location(s), date(s), and time(s) will be published in a forthcoming **Federal Register** notice.

References

A complete list of all references cited herein is available upon request (see **FOR FURTHER INFORMATION CONTACT**).

Classification

National Environmental Policy Act

The 1982 amendments to the ESA, in section 4(b)(1)(A), restrict the information that may be considered when assessing species for listing. Based on this limitation of criteria for a listing decision and the opinion in *Pacific Legal Foundation* v. *Andrus,* 657 F. 2d 829 (6th Cir. 1981), we have concluded that ESA listing actions are not subject to the environmental assessment requirements of the National Environmental Policy Act (See NOAA Administrative Order 216–6).

Executive Order 12866, Regulatory Flexibility Act, and Paperwork Reduction Act

As noted in the Conference Report on the 1982 amendments to the ESA, economic impacts cannot be considered when assessing the status of a species. Therefore, the economic analysis requirements of the Regulatory Flexibility Act are not applicable to the listing process. In addition, this proposed rule is exempt from review under Executive Order 12866. This proposed rule does not contain a collection-of-information requirement for the purposes of the Paperwork Reduction Act.

Executive Order 13132, Federalism

In accordance with E.O. 13132, we determined that this proposed rule does not have significant Federalism effects and that a Federalism assessment is not required. In keeping with the intent of the Administration and Congress to provide continuing and meaningful dialogue on issues of mutual state and Federal interest, this proposed rule will be given to the relevant state agencies in each state in which the species is believed to occur, and those states will be invited to comment on this proposal. We have considered, among other things, Federal, state, and local conservation measures. As we proceed, we intend to continue engaging in informal and formal contacts with the state, and other affected local or regional entities, giving careful consideration to all written and oral comments received.

List of Subjects

50 CFR Part 223

Endangered and threatened species, Exports, Imports, Transportation.

50 CFR Part 224

Endangered and threatened species, Exports, Imports, Transportation.

Dated: March 28, 2013.

Alan D. Risenhoover,

Director, Office of Sustainable Fisheries, performing the functions and duties of the Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR parts 223 and 224 are proposed to be amended as follows:

PART 223—THREATENED MARINE AND ANADROMOUS SPECIES

■ 1. The authority citation for part 223 continues to read as follows:

Authority: 16 U.S.C. 1531–1543; subpart B, § 223.201–202 also issued under 16 U.S.C. 1361 *et seq.;* 16 U.S.C. 5503(d) for § 223.206(d)(9).

■ 2. In § 223.102, paragraphs (c)(30) and (c)(31) are added to read as follows:

§ 223.102 Enumeration of threatened marine and anadromous species.

* * * * *

Species [1]		Where listed	Citation(s) for listing determination(s)	Citation(s) for critical habitat designation(s)
Common name	Scientific name			
*	*	* * *	*	*
(c) * * *				
(30) Scalloped hammerhead shark—Central & SW Atlantic DPS.	*Sphyrna lewini*	Central and Southwest Atlantic Distinct Population Segment. The boundaries for this DPS are as follows: bounded to the north by 28° N. lat., to the east by 30° W. long., and to the south by 36° S. lat. Includes all waters of the Caribbean Sea, comprising the Bahamas' EEZ off the coast of Florida as well as Cuba's EEZ.	[INSERT FR CITATION & DATE WHEN PUBLISHED AS A FINAL RULE].	
(31) Scalloped hammerhead shark—Indo-West Pacific DPS.	*Sphyrna lewini*	Indo-West Pacific Distinct Population Segment. The boundaries for this DPS are as follows: bounded to the south by 36° S. lat., to the west by 15° E. long., and to the north by 40° N. lat. In the east, the boundary line extends from175° W. long. due south to 10° N. lat., then due east along 10° N. lat. to 140° W. long., then due south to 4° S. lat., then due east along 4° S. lat. to 130° W. long, and then extends due south along 130° W. long.	[INSERT FR CITATION & DATE WHEN PUBLISHED AS A FINAL RULE].	
*	*	* * *	*	*

[1] Species includes taxonomic species, subspecies, distinct population segments (DPSs) (for a policy statement, see 61 FR 4722, February 7, 1996), and evolutionarily significant units (ESUs) (for a policy statement, see 56 FR 58612, November 20, 1991).

* * * * *

PART 224—ENDANGERED MARINE AND ANADROMOUS SPECIES

■ 3. The authority citation for part 224 continues to read as follows:

Authority: 16 U.S.C. 1531–1543 and 16 U.S.C. 1361 *et seq.*

■ 4. Amend the table in § 224.101 by adding an entry for Scalloped hammerhead shark—Eastern Atlantic DPS, and by adding an entry for Scalloped hammerhead shark—Eastern Pacific DPS at the end of the table in § 224.101(a) to read as follows:

§ 224.101 Enumeration of endangered marine and anadromous species

* * * * *

(a) * * *

Species [1]		Where listed	Citation(s) for listing determination(s)	Citation(s) for critical habitat designation(s)
Common name	Scientific name			
*	*	* * *	*	*
Scalloped hammerhead shark—Eastern Atlantic DPS.	*Sphyrna lewini*	Eastern Atlantic Distinct Population Segment. The boundaries for this DPS are as follows: Bounded to the west by 30° W. long., to the north by 40° N. lat., to the south by 36° S. lat., and to the east by 20° E. long., but includes all waters of the Mediterranean Sea.	[INSERT FR CITATION & DATE WHEN PUBLISHED AS A FINAL RULE].	NA.
Scalloped hammerhead shark—Eastern Pacific DPS.	*Sphyrna lewini*	Eastern Pacific Distinct Population Segment. The boundaries for this DPS are as follows: bounded to the north by 40° N lat. and to the south by 36° S lat. The western boundary line extends from140° W. long. due south to 10° N., then due west along 10° N. lat. to 140° W. long., then due south to 4° S. lat., then due east along 4° S. lat. to 130° W. long, and then extends due south along 130° W. long.	[INSERT FR CITATION & DATE WHEN PUBLISHED AS A FINAL RULE].	NA.

[1] Species includes taxonomic species, subspecies, distinct population segments (DPSs) (for a policy statement, see 61 FR 4722, February 7, 1996), and evolutionarily significant units (ESUs) (for a policy statement, see 56 FR 58612, November 20, 1991).

* * * * *

[FR Doc. 2013–07781 Filed 4–4–13; 8:45 am]

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Part III

Federal Reserve System

12 CFR Part 242

Definitions of ''Predominantly Engaged In Financial Activities'' and ''Significant'' Nonbank Financial Company and Bank Holding Company; Final Rule

FEDERAL RESERVE SYSTEM

12 CFR Part 242

[Regulation PP; Docket No. R–1405]

RIN 7100–AD64

Definitions of ''Predominantly Engaged In Financial Activities'' and ''Significant'' Nonbank Financial Company and Bank Holding Company

AGENCY: Board of Governors of the Federal Reserve System (''Board'').

ACTION: Final rule.

SUMMARY: The Board is adopting this final rule to establish, for purposes of Title I of the Dodd-Frank Wall Street Reform and Consumer Protection Act (the ''Dodd-Frank Act'' or ''Act''), the requirements for determining if a company is ''predominantly engaged in financial activities''; and definitions of the terms ''significant nonbank financial company'' and ''significant bank holding company.'' These terms are relevant to various provisions of Title I of the Dodd-Frank Act, including section 113, which authorizes the Financial Stability Oversight Council (''Council'') to designate a nonbank financial company for supervision by the Board if the Council determines that the nonbank financial company could pose a threat to the financial stability of the United States.

DATES: The final rule will become effective on May 6, 2013.

FOR FURTHER INFORMATION CONTACT: Laurie Schaffer, Associate General Counsel (202) 452–2272, Paige E. Pidano, Counsel, (202) 452–2803, or Christine E. Graham, Senior Attorney, (202) 452–3005, Legal Division; or Felton C. Booker, Senior Supervisory Financial Analyst, (202) 912–4651, Division of Banking Supervision and Regulation, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW., Washington, DC 20551. Users of Telecommunication Device for Deaf (TDD) only, call (202) 263–4869.

SUPPLEMENTARY INFORMATION:

I. Background

The Dodd-Frank Act established the Council, which, among other authorities and duties, may subject a ''nonbank financial company'' to supervision by the Board and consolidated prudential standards if the Council determines that material financial distress at the nonbank financial company, or the nature, scope, size, scale, concentration, interconnectedness, or mix of the company's activities, could pose a threat to the financial stability of the United States.[1] Nonbank financial companies that are designated by the Council under section 113 of the Dodd-Frank Act are referred to as ''nonbank financial companies supervised by the Board.''[2]

The authority of the Council to subject a nonbank financial company to consolidated prudential supervision by the Board is an important component of recent legislative and regulatory changes designed to address gaps and weaknesses in the financial regulatory system that became evident during the financial crisis. These gaps often allowed financial firms whose failure could pose substantial risks to the financial stability of the United States to avoid prudential, consolidated supervision.

Title I of the Dodd-Frank Act defines a ''nonbank financial company'' to include both a U.S. nonbank financial company and a foreign nonbank financial company. The statute, in turn, defines a ''U.S. nonbank financial company'' as a company (other than a bank holding company and certain other specified types of entities) that is (i) incorporated or organized under the laws of the United States or any State; and (ii) *predominantly engaged in financial activities.*[3] A ''foreign nonbank financial company'' is defined as a company (other than a company that is, or is treated as, a bank holding company) that is (i) incorporated or organized outside the United States; and (ii) *predominantly engaged in financial activities.*[4]

For purposes of Title I of the Dodd-Frank Act, a company is considered to be ''predominantly engaged'' in financial activities if either (i) the annual gross revenues derived by the company and all of its subsidiaries from financial activities, as well as from the ownership or control of an insured depository institution, represent 85 percent or more of the consolidated annual gross revenues of the company; or (ii) the consolidated assets of the company and all of its subsidiaries related to financial activities, as well as related to the ownership or control of an insured depository institution, represent 85 percent or more of the consolidated assets of the company.[5] The Dodd-Frank Act requires the Board to establish the requirements for determining if a company is ''predominantly engaged in financial activities.''[6]

Section 165(d)(2) of the Dodd-Frank Act also requires nonbank financial companies supervised by the Board and bank holding companies with total consolidated assets of $50 billion or more to disclose the nature and extent of (i) the company's credit exposure to other significant nonbank financial companies and significant bank holding companies; and (ii) the credit exposure of such significant entities to the company.[7] The terms ''significant nonbank financial company'' and ''significant bank holding company'' are used in section 113 of the Dodd-Frank Act as well, which specifies that the Council must consider the extent and nature of a nonbank company's transactions and relationships with other ''significant nonbank financial companies'' and ''significant bank holding companies,'' among other factors, in determining whether to designate a nonbank financial company for supervision by the Board.[8] The Act does not define the terms ''significant nonbank financial company'' or ''significant bank holding company,'' but instead directs the Board to define those terms by rule.[9]

On February 11, 2011, the Board invited comment on a proposed rule that would have (i) established the requirements for determining if a company is ''predominantly engaged in financial activities'' for purposes of Title I of the Act and (ii) defined the terms ''significant nonbank financial company'' and ''significant bank

[1] *See* section 113 of the Dodd-Frank Act; 12 U.S.C. 5323.

[2] *See* section 102(a)(4)(D) of the Dodd-Frank Act; 12 U.S.C. 5311(a)(4)(D).

[3] *See* section 102(a)(4)(B) of the Dodd-Frank Act (emphasis added); 12 U.S.C. 5311(a)(4)(B) (emphasis added). Besides bank holding companies, the statute specifically provides that the term ''U.S. nonbank financial company'' does not include (i) a Farm Credit System institution chartered and subject to the Farm Credit Act of 1971 (12 U.S.C. 2001 *et seq.*), (ii) a national securities exchange (or parent thereof), clearing agency (or parent thereof, unless the parent is a bank holding company), security-based swap execution facility, or security-based swap data repository that in each case is registered with the SEC, or (iii) a board of trade designated as a contract market (or parent thereof), or a derivatives clearing organization (or parent thereof, unless the parent is a bank holding company), swap execution facility or a swap data repository that in each case is registered with the CFTC.

[4] *See* section 102(a)(4)(A) of the Dodd-Frank Act (emphasis added); 12 U.S.C. 5311(a)(4)(A) (emphasis added). A foreign bank, or foreign company controlling a foreign bank, is treated as a bank holding company for purposes of the BHC Act if the foreign bank has a branch, agency, or commercial lending company subsidiary in the United States and does not control a U.S. bank.

[5] *See* section 102(a)(6) of the Dodd-Frank Act (emphasis added); 12 U.S.C. 5311(a)(6).

[6] *See* section 102(b) of the Dodd-Frank Act; 12 U.S.C. 5311(b).

[7] *See* section 165(d)(2) of the Dodd-Frank Act; 12 U.S.C. 5365(d)(2).

[8] *See* sections 113(a)(2)(C) and (b)(2)(C) of the Dodd-Frank Act; 12 U.S.C. 5323(a)(2)(C) and (b)(2)(C).

[9] *See* sections 102(a)(7) and (b) of the Dodd-Frank Act; 12 U.S.C. 5311(a)(7) and (b).

holding company'' (''First NPR'').[10] In response to the First NPR, the Board received 23 comments, including comments related to the definition of activities that are financial for purposes of Title I.

Among other things, these comments indicated that some commenters believed that a firm engaged in financial activities could avoid designation simply by choosing not to comply with the conditions imposed on the manner in which those activities must be conducted by bank holding companies. After considering those comments, as well as the language and legislative intent and history of the Dodd-Frank Act and the Bank Holding Company Act (''BHC Act''), as amended by the Gramm-Leach-Bliley Act (''GLB Act''), on April 2, 2012, the Board invited comment on an amendment to the First NPR to clarify that, consistent with the purpose of Title I, any activity referenced in section 4(k) of the BHC Act will be considered to be a financial activity without regard to conditions that do not define whether an activity is itself financial but were imposed on bank holding companies to ensure that the activity is conducted by bank holding companies in a safe and sound manner or to comply with another provision of law (''Second NPR'').[11] In the Second NPR, the Board proposed an appendix of the list of the activities that would be considered to be financial activities as of April 2, 2012, together with conditions the Board believed necessary to define the activity as a financial activity and excluding conditions that the Board believed were related to the safe and sound conduct of the activity, compliance with other law, or other factors not related to whether the activity was financial, for purposes of determining whether a company is predominantly engaged in financial activities. In response to the Second NPR, the Board received 12 comments.

II. Explanation of Final Rule

The final rule provides clarity for purposes of determining whether particular companies qualify as nonbank financial companies under Title I of the Dodd-Frank Act. This is important both in the context of Council designation as well as for large bank holding companies and nonbank financial companies that are required to report their credit exposures to other significant nonbank financial companies pursuant to section 165(d). In developing this final rule, the Board has considered the comments received on both the First and Second NPRs and the language and purposes of the relevant statutory provisions. In addition, the Board consulted with the other Council members and member agencies.

After this review, the Board has determined to adopt the attached final rule, which includes several modifications of the earlier proposals to address matters raised by commenters.

A. Predominantly Engaged in Financial Activities

1. Two-Year Test Based on Consolidated Financial Statements

The First NPR provided that a company would be considered to be predominantly engaged in financial activities if:

- The consolidated annual gross financial revenues of the company in either of its two most recently completed fiscal years represent 85 percent or more of the company's consolidated annual gross revenues (as determined in accordance with applicable accounting standards) in that fiscal year; *or*
- The consolidated total financial assets of the company as of the end of either of its two most recently completed fiscal years represent 85 percent or more of the company's consolidated total assets (as determined in accordance with applicable accounting standards) as of the end of that fiscal year.[12]

Several commenters asserted that the 85 percent threshold in the revenue and asset tests was too high and that a company should be considered to be ''predominantly engaged in financial activities'' if a lower percentage of the company's revenues are derived from, or a lower percentage of its assets are related to, activities that are financial in nature. The statutory language of the Act establishes that a company will be considered to be predominantly engaged in financial activities if either 85 percent of its revenues are derived from, or 85 percent of its assets are related to, financial activities. The Board does not have the discretion to lower the 85 percent threshold established by Congress. Therefore, the final rule retains the revenue and asset tests described above as proposed in the First NPR.

The final rule also retains the proposed definition of ''consolidated annual gross financial revenues'' of a company. A company's consolidated annual gross financial revenues would be determined in accordance with applicable accounting standards, and are that portion of the consolidated annual gross revenues derived directly by the company, or indirectly by any of its consolidated subsidiaries, from: (i) Activities that are financial in nature; or (ii) the ownership, control, or activities of an insured depository institution or any subsidiary of an insured depository institution.[13] Similarly, the final rule retains the proposed definition of ''consolidated total financial assets'' of a company, which is that portion of the company's consolidated total assets, as determined in accordance with applicable accounting standards, that are related to (i) activities that are financial in nature, or (ii) the ownership, control, or activities of an insured depository institution or any subsidiary of an insured depository institution.[14]

As in the First NPR, the final rule provides that computation of assets and revenues for purposes of determining if a company meets the statutory threshold would be based on the relevant company's annual financial revenues in, or financial assets at the end of, either of its two most recent fiscal years. This methodology is designed to account for transitory fluctuations in assets and revenues that may not be indicative of any substantive change in the financial nature of the company or its predominant activities and to allow the Council to effectively fulfill its important responsibilities of designating (and reviewing existing designations of) those nonbank financial companies whose material financial distress could pose a threat to the financial stability of the United States.

2. Activities that are Financial in Nature

The Dodd-Frank Act provides that financial activities are those activities that have been defined as financial in nature in section 4(k) of the BHC Act.[15] In response to issues raised by comments received on the First NPR, the Board invited comment in the Second NPR on a proposal that any activity described in section 4(k) of the BHC Act would be considered financial in nature under Title I regardless of whether the activity is conducted in conformance with conditions imposed on bank holding companies conducting the activity that do not define the financial activity itself, such as conditions related to safety and soundness or related to compliance with another provision of law, such as the Glass-Steagall Act. The Second NPR included an appendix that enumerated the activities and related conditions the Board proposed to retain as part of the

[10] 76 FR 7731 (February 11, 2011).

[11] 77 FR 21494 (April 10, 2012).

[12] *See* § 225.301(a)(1) and (2) of the First NPR and § 242.3(a)(1) and (2) of the Final Rule.

[13] *See* § 242.3(b) of the Final Rule.

[14] *See* § 242.3(c) of the Final Rule.

[15] *See* section 102(a)(6) of the Dodd-Frank Act; 12 U.S.C. 5311(a)(6).

definitions of financial activities under section 4(k) of the BHC Act.

The Board received several comments on the approach taken in the Second NPR. One commenter expressed support for the approach proposed in the Second NPR, while others raised questions regarding the approach. The final rule generally maintains the approach set forth in the Second NPR, with certain modifications that address matters raised by commenters, including the restoration of several conditions the Board proposed to remove in the Second NPR.

The Board also received several comments on the First NPR requesting clarity regarding the relationship between certain types of assets and revenues and financial activities. These comments and the Board's responses are described in greater detail below.

a. Scope of Financial Activities

Some commenters asserted that the Board does not have the authority to issue regulations regarding the scope of activities that are financial in nature for purposes of Title I. One commenter asserted that, while the Dodd-Frank Act expressly provides the Board with rulemaking authority regarding the requirements for determining whether a company is predominantly engaged in financial activities, the Board's rulemaking authority is limited to establishing technical guidelines for calculating a company's financial revenues or assets in assessing whether a particular company and its activities fall within the defined terms of ''predominantly engaged'' and ''financial activities,'' such as identifying the accounting methods that may be used in these calculations.[16]

The Board believes that the approach taken in the Second NPR is authorized under the Dodd-Frank Act's grant of authority to the Board in section 102(b) to establish, by regulation, the requirements for determining if a company is predominantly engaged in financial activities, as defined in section 102(a)(6) of the Dodd-Frank Act.[17] Section 102(a)(6) provides that a company is ''predominantly engaged in financial activities'' if more than 85 percent of the company's and its subsidiaries' annual gross revenues are derived from, or more than 85 percent of the company's and its subsidiaries' consolidated assets are related to, ''activities that are financial in nature'' as defined in section 4(k) of the BHC Act. The identification of the scope of activities that are ''financial in nature'' as defined in section 4(k) of the BHC Act is a necessary requirement for determining whether a company is predominantly engaged in financial activities and, thus, is within the Board's rulemaking authority under section 102(b).

As noted, section 102(a)(6) refers to ''activities that are financial in nature (as defined in section 4(k) of the Bank Holding Company Act of 1956)).'' Section 4(k) of the BHC Act, added by the GLB Act, authorizes bank holding companies that qualify as ''financial holding companies'' to engage in a wide range of financial activities.[18] Section 4(k) defines as ''financial'' a list of Congressionally-authorized activities added by the GLB Act and activities previously approved by the Board for bank holding companies pursuant to sections 4(c)(8) and (13) of the BHC Act, which are incorporated by reference. Section 4(k) and the Board's rules implementing sections 4(c)(8) and (13) also impose conditions on the conduct of some of those activities for safety and soundness reasons or to comply with other provisions of law. Some of the Congressionally-authorized activities for financial holding companies, such as lending, overlap completely with activities that had been authorized by the Board for bank holding companies. Others expanded the authorization of activities previously approved by the Board for bank holding companies, such as certain insurance activities, by removing the conditions that apply to bank holding companies engaging in the activity. Bank holding companies that are not financial holding companies may only engage in activities previously approved by the Board under sections 4(c)(8) and 4(c)(13) of the BHC Act and are subject to the related conditions.

While the BHC Act is clear as to the type and scope of activities that are permissible for each category of bank holding company, section 102(b) of the Dodd-Frank Act is silent as to how the overlapping definitions of financial activities and related conditions incorporated in section 4(k) should be applied in determining whether companies that are not bank holding companies are predominantly engaged in financial activities for purposes of Title I. Because section 102 does not address how to apply these overlapping and sometimes inconsistent definitions of financial activities or how to apply the related conditions incorporated in section 4(k) in assessing the financial activities of nonbank firms, the reference in section 102 of the Dodd-Frank Act to financial activities ''as defined in section 4(k)'' is ambiguous. As the agency with sole authority to ''establish, by regulation, the requirements for determining if a company is predominantly engaged in financial activities, as defined in section 102(a)(6),'' it is appropriate for the Board to resolve this ambiguity.[19]

Under Supreme Court precedent, a statutory term defined by cross-reference to another statute is not alone evidence of clear Congressional intent that the implementing agency construe the term identically. In *Environmental Defense* v. *Duke Energy Corp.* (''*Duke*''),[20] the Court held that the general presumption of statutory construction ''that the same term has the same meaning when it occurs here and there in a single statute,'' may be overcome where context indicates that the term was intended to be construed differently.[21]

Consistent with the Court's analysis in *Duke,* the Board believes that neither the text, the context in which the text appears, nor the legislative purpose or history of the Dodd-Frank Act suggests that Congress intended that a nonbank company must engage in financial activities in compliance with all the conditions and requirements imposed under section 4(k) and the Board's implementing regulations in order for the company to be considered to be engaged in the relevant financial activity. A reading of Title I that limited the scope of companies considered to be ''predominantly engaged in financial

[16] *See* letter dated May 25, 2012, to Jennifer J. Johnson, Secretary, Board of Governors of the Federal Reserve System, from David T. Hirschmann, President and Chief Executive Officer, Center for Capital Markets Competitiveness, U.S. Chamber of Commerce, p. 3.

[17] *See* section 102(b) of the Dodd-Frank Act, 12 U.S.C. 5311(b).

[18] 12 U.S.C. 1843(l)(1). To engage in the broad range of activities authorized by section 4(k), a bank holding company must be well-capitalized and well managed, and its subsidiary insured depository institutions must also be well-capitalized and well-managed and have 'satisfactory' ratings under the Community Reinvestment Act.

[19] *See* section 102(b) of the Dodd-Frank Act, 12 U.S.C. 5311(b).

[20] 549 U.S. 561 (2007).

[21] *See id.* at 574, 576, *citing Atlantic Cleaners & Dyers, Inc.* v. *United States,* 286 U.S. 427, 433. The Court considered whether the Environmental Protection Agency (''EPA'') was required to interpret the term ''modification'' identically where one section of the Clean Air Act (''CAA'') defined ''modification'' ''as defined in'' a different section of the CAA. The Court held that when considering whether a term that is used in different statutes must be interpreted identically, ''context counts.'' *See id.* at 575–76, *citing United States* v. *Cleveland Indians Baseball Co.,* 532 U.S. 200, 213 (2001). The Court considered the context in which the term ''modification'' was used and the legislative history of the relevant statutory provisions and found no evidence of Congressional intent that ''modification'' be construed identically by the EPA despite the cross-reference to the term in the statute because the contexts in which the term was used and the purposes of each use were different.

activities'' to only those companies that conduct activities in compliance with the conditions applicable to bank holding companies would undermine the purpose of Title I and the authority granted by Congress to the Council to protect U.S. financial stability.[22] Defining financial activities for purposes of Title I to include all of the conditions imposed on the conduct of the activities by bank holding companies would lead to the absurd result that some companies that are predominantly engaged in financial activities could avoid consideration for designation by the Council simply by choosing not to abide by one or more conditions that were imposed on bank holding companies to ensure the safe and sound conduct of the activity or compliance with other legal restrictions unrelated to whether the activity is a financial activity.

The Board's proposed approach to addressing the scope of activities is consistent with Congressional intent as reflected in Title I as well as the legislative history of the Dodd-Frank Act. Other sections of Title I support the view that Congress intended that companies could be eligible for designation by the Council regardless of whether these companies complied with the non-definitional conditions applied to bank holding companies in the implementation of section 4(k). For instance, section 167(a) provides that a nonbank financial company supervised by the Board is not required ''to conform its activities to the requirements of section 4 of the BHC Act.'' [23] This section demonstrates that Congress recognized that nonbank financial companies do not conduct their activities in compliance with the requirements applicable to bank holding companies. It would be illogical to conclude that a company would be eligible for Council designation only if it conducted its financial activities in conformance with the requirements imposed on bank holding companies' conduct of financial activities set forth in section 4(k), but would not be required to conform its financial activities to the conditions imposed on bank holding companies by section 4(k) after being designated by the Council for Board supervision.

In addition, the Council's anti-evasion authority demonstrates Congress's intent to give the Council the authority to consider a broad range of nonbank financial companies for designation.[24] Section 113(c) of the Dodd-Frank Act gives the Council the authority to subject the financial activities of *any* company to supervision by the Board if the Council determines, either on its own or pursuant to a recommendation by the Board, that: (i) The company is organized and operates in such a manner to evade application of Title I of the Dodd-Frank Act; and (ii) material financial distress related to, or the nature, scope, size, scale, concentration, interconnectedness, or mix of, the company's financial activities would pose a threat to the financial stability of the United States.[25] Companies that are engaged in activities that are financial in nature, but that alter the manner in which they conduct those activities such that they evade designation by the Council under section 113 and supervision by the Board may be subject to designation by the Council under the special anti-evasion authority in section 113(c).

The legislative history of the Dodd-Frank Act demonstrates that Congress believed that the statutory definition of a ''nonbank financial company'' would make eligible for Council designation companies that were not bank holding companies but that engaged in a broad range of financial activities. For instance, several members of Congress indicated that, while in their view designation may not be appropriate for mutual funds, the activities conducted by mutual funds, which typically do not conform to the prudential conditions imposed on the investment advisory or management activities of bank holding companies, were financial activities for purposes of Title I.[26] In addition, section 165 of the Dodd-Frank Act, which sets forth the enhanced prudential standards applicable to nonbank financial companies designated by the Council, further illustrates that Congress believed that the activities of investment companies were financial activities. Section 165(b)(1)(A)(i) requires the Board to impose risk-based capital requirements and leverage limits on nonbank financial companies designated by the Board and certain bank holding companies, ''unless the Board of Governors, in consultation with the Council, determines that such requirements are not appropriate for a company subject to more stringent prudential standards because of the activities of such company (such as investment company activities or assets under management) or structure, in which case, the Board of Governors shall apply other standards that result in similarly stringent risk controls.'' [27] This statutory requirement indicates that Congress believed that investment company activities were financial.

Moreover, references in section 4(k) itself distinguish between financial activities and the conditions imposed on those activities. Among the activities that section 4(k) defines as being ''financial in nature'' are all of the activities that the Board had determined, by regulation or order, prior to November 12, 1999, to be ''so closely related to banking or managing or controlling banks as to be a proper incident thereto (subject to the same terms and conditions contained in such order or regulation, unless modified by the Board)'' under section 4(c)(8) of the BHC Act.[28] By recognizing that the Board could modify the terms and conditions in the orders and rules authorizing these activities, section 4(k) itself recognizes that these terms and conditions do not necessarily determine whether the activity is a financial activity. Pursuant to section 4(k), an activity authorized under section 4(c)(8) is a financial activity regardless of the conditions imposed by rule or order—all of which may be modified or removed.'' [29]

[22] Committee on Banking, Housing, and Urban Affairs Report, S. Rep. No. 111–176, April 15, 2010, page 3, *citing* Testimony of Timothy Geithner, Secretary of the Treasury, to the Banking Committee, June 18, 2009.

[23] *See* 12 U.S.C. 5367.

[24] *See* 12 U.S.C. 5323(c).

[25] *See id.*

[26] *See,* for example, 156 Cong. Rec. S5873 (daily ed. July 15, 2010) (statement of Sen. Cardin) (indicating that mutual funds and their advisers would be eligible for designation by the Council by stating that section 115 of the Dodd-Frank Act would ''ensure that mutual funds and their advisers are not inadvertently subjected to unworkable standards in the unlikely event the Financial Stability Oversight Council designates [mutual funds] as systemically risky''); *See also* 156 Cong. Rec. S5902–5903 (daily ed. July 15, 2010) (statement of Sen. Kerry) (indicating that although mutual funds and their advisers would be eligible for designation by the Council, regulation by the Board may not be appropriate for such companies because they do not pose a risk to United States financial stability, by stating that ''there are large companies providing financial services that are in fact traditionally low-risk businesses, such as mutual funds and mutual fund advisers'' and that Congress did ''not envision nonbank financial companies that pose little risk to the stability of the financial system,'' such as mutual funds and mutual fund advisers, ''to be supervised by the Federal Reserve'').

[27] *See* section 165(b)(1)(A)(i) of the Dodd-Frank Act; 12 U.S.C. 5365(b)(1)(A)(i).

[28] *See* 12 U.S.C. 1843(k)(4)(F).

[29] Distinguishing between the definition of an activity and conditions imposed for reasons related to other policy and statutory factors is consistent with the Board's long-standing interpretations of the BHC Act, which is the Act to which section 102 of the Dodd-Frank Act refers. For example, in the Board's 1997 revisions to Regulation Y (''1997 rulemaking''), the Board removed several of the conditions imposed on bank holding companies conducting activities that are ''closely related to banking'' by distinguishing between the conditions that were ''necessary to establish the definition of the permitted activity'' and those that were imposed

Continued

One commenter expressed support for the Board's proposal to consider financial activities without regard to the conditions imposed on the conduct of the activities by bank holding companies when considering whether a company is predominantly engaged in financial activities for purposes of Title I.[30] The commenter argued that defining financial activities for purposes of Title I to include all of the conditions imposed on the conduct of the activities by bank holding companies would enable some companies that are predominantly engaged in financial activities to avoid consideration for designation by the Council simply by choosing not to comply with conditions imposed for prudential or other reasons on the manner in which the activities must be conducted by bank holding companies. Some commenters questioned the approach taken in the Second NPR to the extent that it appeared that the approach might cover activities routinely conducted by non-financial firms such as manufacturers or retailers. In these commenters' view, an overly broad interpretation of the definition of financial activities subverts the ''85-percent'' test imposed by statute. In the final rule, the Board has addressed commenters' concerns that activities routinely conducted by non-financial companies could be considered financial through restoration of some of the conditions.

b. Description of ''Financial Activities''

In determining whether or not to include a condition imposed on the scope of an activity or the manner in which an activity may be conducted, the Board considered many factors, including the information and views presented by commenters. The Board also reviewed the statutory language of section 4(k) of the BHC Act and the Board's releases related to the activities that are financial in nature under section 4(k). In addition, the Board reviewed the legislative history of the GLB Act, which itself removed or modified many of the conditions applicable to the conduct of financial activities by bank holding companies and financial holding companies.[31]

As an initial matter, the Board notes that the only role of this rulemaking is to define activities that are financial. This rulemaking does not designate any specific entity for enhanced supervision under Title I of the Dodd-Frank Act. Authority to designate an entity for enhanced supervision rests exclusively with the Council. Thus, clarity regarding whether any specific entity will be designated under Title I must come from other agencies.[32]

In the Second NPR, the Board noted that the list of financial activities authorized under section 4(k) included overlapping and redundant activities, and invited comment on whether overlapping or redundant financial activities should be combined or removed, as appropriate, solely for purposes of determining whether a nonbank company is predominantly engaged in financial activities, in order to reduce the ambiguity created by these overlapping and sometimes inconsistent activities and to simplify the proposed appendix. The Board did not receive comment on this request, and, consistent with the Second NPR, the Board has maintained the complete list of financial activities authorized under section 4(k), including the overlapping and redundant activities, in order to ensure completeness and to avoid confusion based on the specific statutory authority relied on in defining an activity. To reduce the ambiguity created by the overlapping and redundant descriptions of financial activities included in the appendix, a company that engages in a particular activity in a manner that does not comply with the narrower definition of the particular activity will be considered to be engaged in a financial activity if its activities are captured by the broader description of the activity.

The following discussion describes the activities enumerated in the appendix to the final rule that are financial in nature as defined in section 4(k) of the BHC Act for purposes of determining whether a company is predominantly engaged in financial activities. The discussion also identifies the conditions imposed in section 4(k) or by the Board's implementing regulations pursuant to sections 4(c)(8) and (13) that are not reflected in the appendix because they were imposed for safety and soundness considerations or to comply with other provisions of law and, thus, are not relevant for determining whether these activities are considered financial for purposes of determining whether a firm is predominantly engaged in financial activities. As noted previously, the final rule reinstates several conditions that the Board proposed to remove from the definitions of financial activities in the Second NPR. The final rule retains all of the conditions set forth in the description of financial activities specifically enumerated under section 4(k), other than two conditions with respect to the activity of investing as part of a bona fide underwriting or merchant or investment banking activity, and one condition with respect to insurance company portfolio investments, which do not define the activity itself and were imposed for safety and soundness reasons and to ensure compliance with other provisions of law.

i. Financial activities added to the BHC Act by the GLB Act

The following financial activities were authorized for financial holding companies and added to section 4(k) of the BHC Act by the GLB Act. These activities are financial activities for purposes of determining whether a firm is predominantly engaged in financial activities under Title I.

for other purposes, such as ''to prevent circumvention of another statute, such as the Glass-Steagall Act. *See* 62 FR 9290, 9305 (February 28, 1997). The Board stated that the revisions made by the 1997 rulemaking were necessary to remove conditions that ''[were] outmoded, [were] superseded by Board order, or [did] not apply to insured depository institutions conducting those same activities,'' and the conditions retained in section 225.28 were ''necessary to establish the definition of the permitted activity or to prevent circumvention of another statute, such as the Glass-Steagall Act.'' The Board further noted that its ''removal of [such] restrictions from the regulation does not affect the Board's determination that'' these activities are ''so closely related to banking as to be a proper incident thereto'' and thus permissible for bank holding companies.

[30] *See* letter dated May 24, 2012, to Jennifer J. Johnson, Secretary, Board of Governors of the Federal Reserve System, from Christopher Cole, Senior Vice President and Senior Regulatory Counsel, Independent Community Bankers of America.

[31] In amending Regulation Y consistent with the GLB Act, the Board noted that the GLB Act eliminated many of the ''detailed restrictions on relationships and transactions between depository institutions and securities affiliates'' that had been required prior to the passage of the GLB Act. *See* 65 FR 14440, 14441 (March 17, 2000). The Board also noted that in light of the GLB Act ''securities underwriting, dealing, and market making * * * is authorized for financial holding companies in a broader form'' than had previously been permitted. *See id.* at 14433, 14435 (March 17, 2000).

[32] As noted previously, Title I of the Dodd-Frank Act authorizes the Council to take certain actions with respect to nonbank financial companies, including designating a nonbank financial company for Board supervision pursuant to section 113 and issuing recommendations under section 120 to a primary financial regulatory agency to apply new or heightened standards to a financial activity conducted by nonbank financial companies under the jurisdiction of that regulatory agency. A nonbank financial company is a company that is predominantly engaged in financial activities. Therefore, the application of the definitions of financial activities and the determination that a company is predominantly engaged in financial activities will be subject to review by the Council with respect to an action taken by the Council involving nonbank financial companies under Title I of the Dodd-Frank Act. 12 U.S.C. 5323(a) and (b). The Dodd-Frank Act provides a specific procedure in the designations process under which a company may challenge the Council's proposed determination that the nonbank financial company could pose a threat to U.S. financial stability and shall be subject to Board supervision. 12 U.S.C. 5323(e) and (h).

• Lending, Exchanging, Transferring, Investing for Others, and Safeguarding Money or Securities

The activities of lending, exchanging, transferring, investing for others, or safeguarding money or securities are specifically enumerated, without conditions, in section 4(k) of the BHC Act.[33] The activity of ''investing for others'' includes buying, selling, or otherwise acquiring and disposing of money or securities in order to benefit from changes in the value of those assets and distribute profits to investors. These activities are often conducted by investment advisors, wealth managers, limited purpose trust companies, mutual funds, hedge funds, private equity funds, real estate investment trusts, and similar vehicles.

One commenter asserted that the Board had not authorized bank holding companies to control or be an open-end investment company and that, as a result, open-end investment companies cannot be found to be engaged in financial activities as defined in section 4(k) of the BHC Act. The commenter argued that open-end investment companies (e.g., mutual funds) are not engaged in a financial activity as defined in section 4(k) of the BHC Act, and that the Board should ''reduce uncertainty created by the ambiguity in Title I * * * to make clear to investors and the public that [money market mutual funds] will *not* be designated * * * under Title I'' of the Dodd-Frank Act.[34] The crux of this commenter's argument is the assertion that the Board has not issued any order approving an application or request by a bank holding company to be or to control a mutual fund[35] and therefore such activities cannot be considered to be financial.

The Board believes that it is clear that open-end investment companies, such as mutual funds including money market funds, as well as closed-end investment companies, engage in financial activities as defined in section 4(k) of the BHC Act. The Board's regulations have long authorized bank holding companies to engage in organizing, sponsoring, and managing mutual funds and closed-end investment companies and serving as an investment adviser to mutual funds and closed-end investment companies and others using authority described in section 4(k) of the BHC Act.[36] As the commenter recognized, prior to enactment of the GLB Act in 1999, the Board permitted bank holding companies to own more than 5 percent (and up to 25 percent) of the shares of an open-end investment company—a determination that represents a finding that open-end investment companies engage in a financial activity.[37] The investment limitation reflects a decision by the Board that the public benefits of allowing a bank holding company to own more than 25 percent of the shares of a mutual fund did not outweigh the potential costs consequent with treating the mutual fund as a subsidiary of the bank holding company. Under the BHC Act, the decision to allow a bank holding company to own more than 5 percent of the shares of a mutual fund is sufficient to indicate that the mutual fund itself, which is a company, is engaged in a financial activity.[38] The activity of organizing, sponsoring, and managing a mutual fund was also determined to be usual in connection with the transaction of banking or other financial operations abroad prior to November 11, 1999, and, thus, is incorporated as a financial activity in section 4(k) by the GLB Act.[39] The Board's regulations prohibit bank holding companies from exerting managerial control over the companies in which the mutual fund invests and require bank holding companies to reduce their ownership to less than 25 percent of the equity of the mutual fund within one year of sponsoring the fund.[40] These limitations were imposed to prevent circumvention of the investment restrictions in the BHC Act.

Moreover, section 4(k) itself authorizes all of the component activities in which a mutual fund engages—investing for others,[41] merchant banking,[42] investment advice,[43] and underwriting[44]—as financial. These activities are defined as financial under section 4(k) separately from, and in addition to, those activities previously approved by the Board as being so closely related to banking as to be a proper incident thereto, or usual in connection with the transaction of banking or other financial operations abroad, which are incorporated into the definition of financial activities in section 4(k).[45]

Section 4(k) specifically defines the activities of underwriting, dealing in, or making a market in securities as a financial activity, which includes key components of sponsoring and distributing mutual funds and investment companies. Section 4(k) also specifically enumerates as financial activities providing financial, investment, and economic advisory services and investing for others, which includes buying, selling, or otherwise acquiring and disposing of money or securities in order to benefit from changes in the value of those assets and distribute profits to investors. Similarly, section 4(k) authorizes merchant banking activities—which represent investments made for the purpose of profiting from price appreciation—as financial.

The fact that the Board has imposed prudential conditions on bank holding companies engaged in the activity of organizing, sponsoring, or managing a mutual fund does not negate the fact that the activity is financial for purposes of section 4(k).[46] Moreover, while open-end investment companies (and other investment vehicles) have not applied to become bank holding companies, the Board does not believe that this in any way reflects a judgment that the companies are not engaged in financial activities. It is more likely a reflection that open-end investment companies (and similar investment vehicles) have chosen not to control banks in order to avoid the capital, risk management, and other supervisory requirements attendant to becoming a bank holding company.

• Insurance Activities

Insuring, guaranteeing, or indemnifying against loss, harm, damage, illness, disability, or death, or providing and issuing annuities, and acting as principal, agent, or broker for purposes of the foregoing, in any state,

[33] 12 U.S.C. 1843(k)(4)(A).

[34] *See* letter dated March 30, 2011, to Jennifer J. Johnson, Secretary, Board of Governors of the Federal Reserve System, from John D. Hawke, Jr., Arnold & Porter LLP, p. 7 (emphasis in original).

[35] *See id.* at p. 8.

[36] *See, e.g.,* 12 CFR 211.10(a)(11); 225.28(b)(6)(i); 225.86(b)(3); and 225.125. *See also, e.g., Mellon Bank Corporation,* 79 *Federal Reserve Bulletin* 626 (1993), and *Bayerische Vereinsbank AG,* 73 *Federal Reserve Bulletin* 155 (1987).

[37] *See* letter dated June 24, 1999, to H. Rodgin Cohen, Esq., Sullivan & Cromwell (First Union Corporation), from Jennifer J. Johnson, Secretary of the Board of Governors of the Federal Reserve System. *See* also 12 CFR 225.86(b)(3).

[38] Bank holding companies are generally prohibited from owning more than 5 percent of the voting shares of a company unless that company is engaged only in a financial activity. *See* 12 U.S.C. 1843(a).

[39] 12 U.S.C. 1843(k)(4)(G); 12 CFR 225.86(b)(3).

[40] 12 CFR 225.86(b)(3).

[41] 12 U.S.C. 1843(k)(4)(A).

[42] 12 U.S.C. 1843(k)(4)(H).

[43] 12 U.S.C. 1843(k)(4)(C).

[44] 12 U.S.C. 1843(k)(4)(E).

[45] In amending Regulation Y consistent with the GLB Act, the Board added the financial activities added to section 4(k) by the GLB Act and noted that in light of the passage of the GLB Act ''securities underwriting, dealing, and market making * * * is authorized for financial holding companies in a broader form'' than had previously been permitted. *See* 65 FR 14440, 14443, 14435 (March 17, 2000).

[46] As noted previously, bank holding companies are generally prohibited from owning more than 5 percent of the voting shares of a company unless that company is engaged only in a financial activity. *See* 12 U.S.C. 1843(a).

are financial activities specifically enumerated in section 4(k) of the BHC Act.[47]

• Financial, Investment, and Economic Advisory Services

Financial, investment, and economic advisory services are financial activities specifically enumerated in section 4(k) of the BHC Act.[48] These activities may be provided individually or in combination and include discretionary and non-discretionary investment advisory activities. This broad authorization to provide financial, investment, or economic advisory services also includes activities that the Board previously determined were closely related to banking. For example, the Board determined that acting as an investment or financial advisor to any person was closely related to banking, including, without limitation, the activities of sponsoring, organizing, and managing a closed-end investment company, such as a hedge fund, and furnishing general economic information and advice.[49] The Board also previously determined that providing administrative and other services to mutual funds could be provided in connection with acting as an investment or financial advisor as activities that were closely related to banking, as described further below.

• Issuing or Selling Instruments Representing Interests in Pools of Bank-Permissible Assets

Issuing or selling instruments representing interests in pools of assets permissible for a bank to hold directly is a financial activity specifically enumerated in section 4(k) of the BHC Act.[50]

• Underwriting, Dealing, and Market Making

Underwriting, dealing in, or making a market in securities is a financial activity specifically enumerated in section 4(k) of the BHC Act,[51] which includes sponsoring and distributing all types of mutual funds and investment companies.[52]

• Merchant Banking

Section 4(k)(4)(H) of the BHC Act describes the financial activity of acquiring or controlling shares, assets or ownership interests, including debt or equity securities, in a company engaged in any activity not authorized under section 4 of the BHC Act ''as part of a bona fide underwriting or merchant or investment banking activity, including investment activities engaged in for the purpose of appreciation and ultimate resale or disposition of the investment'' [53] (''merchant banking''). Section 4(k)(4)(H) imposes several requirements on financial holding companies seeking to engage in merchant banking activities. In particular, (i) the shares may not be acquired or held by a depository institution; (ii) the shares must be acquired and held by a securities affiliate or an affiliate thereof, or in the case of a financial holding company that has an insurance company affiliate, by an affiliate that provides investment advice to an insurance company and is registered pursuant to the Investment Advisers Act of 1940, or an affiliate thereof; (iii) the shares must be held as part of a bona fide underwriting or merchant or investment banking activity, including investment activities engaged in for the purpose of appreciation and ultimate resale or disposition of the investment; (iv) the shares are held for a period of time to enable the sale or disposition on a reasonable basis consistent with the financial viability of the company's underwriting, merchant, or investment banking activities; and (v) during the period the shares are held, the bank holding company does not routinely manage or operate the company except as may be necessary to obtain a reasonable return on investment upon resale or disposition.[54]

The condition in section 4(k)(4)(H) requiring that the shares only be held for a period of time to enable their sale or disposition on a reasonable basis consistent with the financial viability of the company's merchant banking activities is an essential element of a bona fide merchant banking activity. Thus, this condition is reflected in the appendix. Bona fide merchant banking activities involve investing with the intent to sell the investment at some later point in time at which a profit is expected to be realized. For example, companies such as hedge funds, mutual funds, and private equity firms [55] that are engaged in bona fide merchant banking activities typically make investments in companies that they believe will increase in value over time and that can be resold at a profit. Hedge funds, mutual funds, and private equity funds invest with the expectation of selling those instruments at a future date in order to realize profits consistent with a particular investment strategy rather than for the purpose of owning and operating the business.

The Board and the Secretary of the Treasury jointly issued regulations adopting holding periods for merchant banking investments by financial holding companies pursuant to section 4(k)(4)(H).[56] Specific time periods are not set forth in section 4(k) of the BHC Act. As such, they are not included in the definition of merchant banking for purposes of Title I. Nevertheless, the time periods adopted by the Board and the Secretary of the Treasury are instructive in determining whether a nonbank company is engaged in bona fide merchant banking activities. Thus, for purposes of determining whether a nonbank company is predominantly engaged in financial activities under Title I, nonbank companies that acquire and hold shares for the period permitted for financial holding companies under the Board's regulations will be presumed to be holding the shares for the purpose of appreciation and ultimate resale or disposition in accordance with the condition in section 4(k)(4)(H). This presumption will help companies determine whether they are predominantly engaged in financial activities. In addition, this presumption will reduce burden on companies that are required to report their credit exposure to significant bank holding companies and significant nonbank financial companies under section 165(d) of the Dodd-Frank Act.[57]

[47] 12 U.S.C. 1843(k)(4)(B). In amending Regulation Y consistent with the GLB Act, the Board noted that section 4(k)(4) authorized financial activities, including ''activities that previously have not been permissible for bank holding companies, such as acting as principal, agent, or broker for purposes of insuring, guaranteeing, or indemnifying against loss, harm, damage, illness, disability, or death, and issuing annuity products. Permissible insurance activities as principal include reinsuring insurance products. A financial holding company acting under that section may conduct insurance activities without regard to the restrictions on the insurance activities imposed on bank holding companies under section 4(c)(8).'' *See* 65 FR 14433, 14435 (March 17, 2000).

[48] 12 U.S.C. 1843(k)(4)(C).

[49] *See* 12 CFR 225.28(b)(6) and 225.125.

[50] 12 U.S.C. 1843(k)(4)(D).

[51] 12 U.S.C. 1843(k)(4)(E).

[52] *See* H.R. Rep. No. 106–434 at 153 (1999) (Conf. Rep.)

[53] 12 U.S.C. 1843(k)(4)(H).

[54] *See id.*

[55] *See* H.R. Rep. No. 106–434 at 154 (1999) (Conf. Rep.) (describing the merchant banking authority under section 4(k)(4)(H) as authorizing a financial holding company (''FHC'') to acquire an ownership interest ''in an entity engaged in any kind of trade or business whatsoever * * * whether acting as principal, on behalf of one or more entities (e.g., as adviser to a fund, regardless of whether the FHC is also an investor in the fund), including entities that the FHC controls (other than a depository institution or a subsidiary of a depository institution), or otherwise.'').

[56] *See* 12 CFR 225.172 and 12 CFR 1500.3, respectively.

[57] As previously discussed, section 165(d)(2) requires nonbank financial companies supervised by the Board and bank holding companies with total consolidated assets of $50 billion or more to submit reports to the Board, the Council, and the

The Board recognizes that some investment vehicles may hold shares for longer periods as part of a bona fide merchant banking activity consistent with the vehicle's investment strategy. For this reason, the Council, with respect to the definition of a nonbank financial company for purposes of Title I, or the Board, with respect to the definition of a significant nonbank financial company, also may determine, on a case-by-case basis, that a company that acquires and holds shares for a period of time greater than the period permissible for a financial holding company is engaged in bona fide merchant banking activities for purposes of determining whether the company is predominantly engaged in financial activities.

The prohibition in section 4(k)(4)(H) on routinely managing a portfolio company, other than for purposes of recognizing a reasonable return on resale or disposition, is an essential element of bona fide merchant banking activities. Thus, this prohibition is reflected in the appendix. As previously discussed, companies engaging in these activities purchase shares of portfolio companies to recognize an ultimate profit, rather than to engage in the underlying activity in which the portfolio company engages as its primary business activity. Routinely managing the companies, other than for the goal of recognizing a reasonable return, may indicate a strategic investment in the operations of another firm.

Section 4(k) does not define the statutory prohibition of routinely managing a portfolio company. The regulations issued by the Board and the Secretary of the Treasury governing the merchant banking activities of financial holding companies provide guidance on the statutory prohibition of routinely managing a portfolio company in connection with a bona fide merchant banking activity. These regulations are instructive in determining whether a nonbank company is engaged in bona fide merchant banking activities. Therefore, for purposes of determining whether a nonbank company is predominantly engaged in financial activities under Title I, nonbank companies that comply with this guidance regarding the limitations on managing or operating a portfolio company will be presumed to be engaged in a bona fide merchant banking activity. This presumption will reduce burden on companies attempting to determine whether they, or certain of their counterparties,[58] are predominantly engaged in financial activities. The Council or the Board, as appropriate, also may determine, on a case-by-case basis, that an entity that does not comply with the Board's guidance regarding this limitation may still be engaged in a bona fide merchant banking activity for purposes of determining whether the company is predominantly engaged in financial activities.

By contrast, the condition in section 4(k)(4)(H) requiring a financial holding company engaging in merchant banking activities to have a securities affiliate is not an essential element of bona fide merchant banking activities for determining whether these activities are financial activities.[59] This is evidenced by the fact that section 4(k) does not require that the securities affiliate participate in or play a role with respect to these activities. This condition was designed to ensure that only those financial holding companies with experience engaging in investment, securities, or advisory activities conducted merchant banking activities. Accordingly, this condition is not reflected in the appendix.

Similarly, the condition in section 4(k)(4)(H) requiring that shares acquired as part of a bona fide merchant banking activity not be acquired or held by a depository institution is not an essential element of such activities, and thus is not reflected in the appendix. This restriction was imposed because banks are restricted from investing in certain types of companies by statute and regulation, and in particular, national banks were prohibited by the GLB Act from engaging in merchant banking activities through a financial subsidiary unless certain findings were made by the Secretary of the Treasury and the Board.[60] The restriction on acquiring or holding investments through a depository institution does not define the activity of merchant banking but rather imposes conditions on holding the investment through one type of corporate affiliate. The condition does not define the activity itself, as financial holding companies, which have bank affiliates, engage in these activities on a regular basis.

Finally, section 4(k)(4)(H) provides that shares acquired in connection with a bona fide merchant banking activity must be those of a company engaged in an activity not authorized under section 4 of the BHC Act. This provision provided new authority for bank holding companies that qualify as financial holding companies to engage in merchant banking activities with regard to nonbanking firms; bank holding companies were already authorized under other provisions of section 4 of the BHC Act to invest in firms engaged in financial activities.[61] For this reason, the Board has retained this reference to an ''activity not authorized under section 4 of the BHC Act'' in the description of bona fide merchant banking activities. An investment in a company engaged in activities otherwise permissible under section 4 would otherwise be treated as a financial activity under section 4(k)(1) or other provisions of section 4(k). Thus, shares acquired in all types of firms in connection with a bona fide merchant banking activity are effectively included by section 4(k) within the list of permissible financial activities.

• Insurance Company Portfolio Investments

Section 4(k)(4)(I) of the BHC Act authorizes companies engaged in certain types of insurance activities to make portfolio investments. In particular, financial holding companies are authorized to acquire assets or ownership interests, including debt or equity securities, of a company or other entity engaged in any activity not

FDIC on the nature and extent of (i) the company's credit exposure to other significant nonbank financial companies and significant bank holding companies; and (ii) the credit exposure of such significant entities to the company. In order to comply with this reporting obligation, companies required to report their credit exposure to significant nonbank financial companies must be able to identify those companies that are predominantly engaged in financial activities, and thus, considered to be nonbank financial companies.

[58] *See id.*

[59] The legislative history related to Congress's authorization of ''underwriting, merchant, and investment banking activities'' distinguishes between the activities themselves and certain conditions imposed on the conduct of these activities by a financial holding company that do not define the activities, such as the requirement that a financial holding company have a securities affiliate. *See* Conf. Rep. 106–434, 154 (November 2, 1999). (''The authorization of merchant banking activities as provided in new section 4(k)(4)(H) of the BHCA is designed to recognize the essential role *that these activities* play in modern finance and permits an FHC that has a securities affiliate or an affiliate of an insurance company engaged in underwriting life, accident and health, or property and casualty insurance, or providing and issuing annuities, *to conduct such activities.''*) (emphasis added).

[60] *See, e.g.,* 12 U.S.C. 24, (Seventh); 12 U.S.C. 24, (Eleventh); 12 CFR 1.

[61] *See* 65 FR 16460, 16463–16464 (March 28, 2000), in which the Board noted that the provision in section 4(k)(4)(H) that authorizes a financial holding company to invest in any company engaged in any activity not authorized pursuant to section 4 of the BHC Act ''appears to have been included in recognition of the fact that other provisions of the BHC Act permit a financial holding company to make investments in companies that conduct financial activities without resorting to merchant banking authority.''

authorized by section 4(k) if: (i) The shares, assets, or ownership interests are not acquired or held by a depository institution or a subsidiary of a depository institution; (ii) such shares, assets, or ownership interests are acquired and held by an insurance company that is predominantly engaged in underwriting life, accident and health, or property and casualty insurance (other than credit-related insurance) or providing and issuing annuities; (iii) such shares, assets, or ownership interests represent an investment made in the ordinary course of business of such insurance company in accordance with relevant state law governing such investments; and (iv) during the period such shares, assets, or ownership interests are held, the bank holding company does not routinely manage or operate such company except as may be necessary or required to obtain a reasonable return on investment.[62]

The conditions in section 4(k)(4)(I) requiring that the shares (i) be acquired and held by an insurance company engaged in particular activities, (ii) in the ordinary course of business of the acquiring insurance company in accordance with relevant state law governing such investments, are essential elements of this activity, which was authorized by Congress specifically to permit ''an insurance company that is affiliated with a depository institution to continue to directly or indirectly acquire or control any kind of ownership interest in any company,'' in recognition of the fact ''that as part of the ordinary course of business, insurance companies frequently invest funds received from policyholders by acquiring most or all the shares of stock of a company that may not be engaged in a financial activity.'' [63] Thus, these conditions are reflected in the appendix. In contrast to merchant banking activities described in section 4(k)(4)(H), which requires a financial holding company engaging in such activities to have a securities affiliate, but does not require that the securities affiliate play a role in the activities, section 4(k)(4)(I) requires that the investment activities authorized thereunder be conducted *by or through an insurance company*.

The prohibition in section 4(k)(4)(I) on routinely managing a portfolio company, other than for purposes of recognizing a reasonable return on the investment, is an essential element of the investment activities conducted by insurance companies. Thus, this prohibition is reflected in the appendix. As noted previously, insurance companies typically invest policyholder funds in other companies in the ordinary course of business pursuant to state insurance laws. Routinely managing the companies, other than for the purpose of recognizing a return on investment, may indicate a strategic investment in the operations of the other company.[64]

Section 4(k)(4)(I) requires that shares acquired pursuant to an insurance company's investment activities not be acquired or held by a depository institution. This condition is not an essential element of this activity, and, thus, is not reflected in the appendix. The restriction on acquiring or holding investments through a depository institution does not define the investment activity described in section 4(k)(4)(I), but rather imposes conditions on holding the investment through one type of corporate affiliate. As discussed previously, section 4(k)(4)(I) requires that the investment activities authorized thereunder be conducted by or through an insurance company. In addition, as noted previously, banks are restricted from investing in certain types of companies by statute and regulation.[65] The condition does not define the activity itself, as insurance companies affiliated with depository institutions engage in these activities on a regular basis.[66]

Finally, as in section 4(k)(4)(H), section 4(k)(4)(I) provides that shares acquired by an insurance company in connection with its investment activities must be those of a company engaged in an activity not authorized under section 4 of the BHC Act. For the same reasons described above, the Board has retained this reference to an ''activity not authorized under section 4 of the BHC Act'' in the description of the investment activities of insurance companies pursuant to section 4(k)(4)(I). An investment in a company engaged in activities otherwise permissible under section 4 would otherwise be treated as a financial activity under section 4(k)(1) or other provisions of section 4(k). Thus, investments by insurance companies in all types of firms are effectively included by section 4(k) within the list of permissible financial activities.

- Lending, Exchanging, Transferring, Investing for Others, Safeguarding Financial Assets Other Than Money or Securities, and Other Activities

The activities of lending, exchanging, transferring, investing for others, or safeguarding financial assets other than money or securities; providing any device or other instrumentality for transferring money or other financial assets; and arranging, effecting, or facilitating financial transactions for the account of third parties are financial activities specifically enumerated in section 4(k)(5) of the BHC Act.[67]

ii. Financial Activities That Are Closely Related to Banking

Section 4(k) provides that ''any activity that the Board has determined to be so closely related to banking or managing or controlling banks as to be a proper incident thereto'' is a financial activity.[68] These activities are also financial for purposes of determining whether a firm is predominantly engaged in financial activities under Title I. These activities include the following:

- Extending Credit and Servicing Loans

Making, acquiring, brokering, or servicing loans or other extensions of credit (including factoring, issuing letters of credit and accepting drafts) for the company's account or for the account of others were authorized by the Board as activities that are closely related to banking.[69]

- Activities Related to Extending Credit

Activities usual in connection with making, acquiring, brokering, or servicing loans or other extensions of credit were authorized by the Board as

[62] 12 U.S.C. 1843(k)(4)(I).

[63] *See* H.R. Rep. No. 106–434 at 154 (1999) (Conf. Rep.) (further describing section 4(k)(4)(I) as recognizing that ''these investments are made in the ordinary course of business pursuant to state insurance laws governing investments by insurance companies, and are subject to ongoing review and approval by the applicable state regulator'').

[64] *See id.* at 155 (noting that ''to the extent an FHC participates in the management or operation of a portfolio company, such participation would ordinarily be for the purpose of safeguarding the investment of the insurance company in accordance with applicable state insurance law. This is irrespective of any overlap between board members and officers of the FHC and the portfolio company'').

[65] *See, e.g.,* 12 U.S.C. 24, (Seventh); 12 U.S.C. 24, (Eleventh); 12 CFR part 1.

[66] As discussed above, section 4(k)(4)(I) was intended to permit ''an insurance company that is affiliated with a depository institution to continue to directly or indirectly acquire or control any kind of ownership interest in any company if certain requirements are met.'' *See* H.R. Rep. No. 106–434 at 154 (1999) (Conf. Rep.).

[67] 12 U.S.C. 1843(k)(5). The BHC Act requires the Board to define the extent to which these activities are financial in nature or incidental thereto. The Board and the Secretary of the Treasury issued a joint interim rule authorizing such activities as permissible for financial holding companies. *See* 66 FR 257 (January 3, 2001).

[68] 12 U.S.C. 1843(k)(4)(F).

[69] 12 U.S.C. 1843(k)(4)(F); 12 CFR 225.28(b)(1). *See* 62 FR 9290, 9305 (February 28, 1997), in which the Board noted that ''[l]ending activities are already broadly defined and contain no restrictions.''

activities that are closely related to banking.[70] These activities include performing appraisals of real estate and personal property (including securities), acting as an intermediary for commercial or industrial real estate financing, providing check guarantee, collection agency, and credit bureau services, engaging in asset management, servicing, and collection activities, acquiring debt in default, and providing real estate settlement services.[71]

The Board's regulations impose certain conditions on the conduct of these activities that are not relevant for determining whether these activities are considered financial for purposes of determining whether a firm is predominantly engaged in financial activities. For instance, under the Board's regulations, a bank holding company that is arranging financing for commercial or industrial income-producing real estate may not have an interest in, participate in managing or developing, or promote or sponsor the development of a property for which it is arranging financing, or engage in property management or real estate brokerage.[72] These conditions were imposed to clarify that real property management and real estate brokerage activities—which were not at the time found to be financial activities—are not indirectly authorized as permissible for bank holding companies through the activity of real estate financing.[73] As such, the appendix reflects the activity of arranging commercial real estate financing without reference to the independent activities of owning, managing, developing, or promoting or sponsoring development of real estate.[74] While neither real estate brokerage nor real estate management are financial activities under section 4(k), a company may engage in these activities and still be predominantly engaged in the financial activity of arranging commercial real estate financing. Under the final rule, only assets and revenues associated with this latter activity are considered financial for purposes of determining whether a firm is predominantly engaged in financial activities.

Acquiring debt in default also is a financial activity for purposes of determining whether a firm is predominantly engaged in financial activities under Title I as it is an activity that is usual in connection with making, acquiring, brokering, or servicing loans or other extensions of credit.[75] Under the Board's regulations, a bank holding company that acquires debt in default must divest assets securing the debt that are impermissible for bank holding companies to hold within a certain time period, stand only in the position of a creditor, not purchase equity of obligors of debt in default, and not acquire debt in default secured by shares of a bank or bank holding company. These conditions are intended to prevent bank holding companies from circumventing the BHC Act and other provisions of law. For instance, the condition requiring a bank holding company to divest impermissible assets within a certain timeframe was intended to distinguish between a bank holding company's acquisition of debt in default and its retention of impermissible collateral securing the debt.[76] The conditions requiring the bank holding company to stand only in the position of a creditor and not purchase equity of obligors of debt in default are intended to prevent a bank holding company from acquiring assets in connection with a debt previously contracted the ownership of which is prohibited by the BHC Act or other provisions of law. These conditions are not related to defining the financial nature of the activity of acquiring debt in default.[77] The condition requiring that the debt not be secured by shares of a bank or bank holding company was imposed to prevent the bank holding company from circumventing the BHC Act's requirement that a bank holding company obtain approval from the Board before acquiring control of another bank or bank holding company.[78] For these reasons, these conditions are not relevant for determining whether the assets and revenues associated with these activities are considered financial for purposes of determining whether a firm is predominantly engaged in financial activities. The appendix provides that the activity of acquiring debt that is in default at the time of acquisition is a financial activity for purposes of determining whether a company is predominantly engaged in financial activities under Title I without reference to these conditions.

• Leasing

Leasing personal or real property, and acting as an agent, broker, or adviser for leasing personal or real property were determined to be closely related to banking by the Board.[79] Under the Board's regulations, permissible leasing must involve a lease that is on a nonoperating basis with an initial term of at least 90 days. In addition, leasing involving real property must have the effect of yielding a return that will compensate the lessor for not less than the lessor's full investment plus the estimated cost of financing the property over the term of the lease, and the property must have an estimated residual value that is no more than 25 percent of the acquisition cost of the property. The conditions serve to distinguish between the financial activity of leasing and the nonfinancial activities of real or personal property rental and real estate management.[80] As such, the appendix reflects these conditions in defining the activities of leasing and acting as an agent, broker, or adviser for personal or real property.

• Operating Nonbank Depository Institutions

The activity of owning, controlling, and operating depository institutions, including industrial banks, Morris Plan banks, industrial loan companies and savings associations that do not qualify as ''banks'' for purposes of the BHC Act was determined to be closely related to banking by the Board.[81] While the Board's regulations require that a thrift owned, controlled, or operated by a bank holding company be engaged only in deposit-taking activities and activities permissible for bank holding companies, the appendix does not include these conditions because they are inconsistent with section 102 of the

[70] 12 U.S.C. 1843(k)(4)(F); 12 CFR 225.28(b)(2).

[71] *Id.*

[72] 12 U.S.C. 1843(k)(4)(F); 12 CFR 225.28(b)(2)(ii).

[73] The Board first approved the application of a bank holding company to engage in real estate equity financing in 1982. In approving this activity, the Board noted that it had imposed conditions, including that the bank holding company not have an interest in, participate in managing or developing, or promote or sponsor the development of a property for which it is arranging financing, ''to confine the activity * * * to equity financing and to prevent [the bank holding company] from engaging in real estate development * * *'' *See BankAmerica Corporation,* 68 Federal Reserve Bulletin 647 (1982). The activity of arranging commercial real estate equity financing was added to Regulation Y in 1984 and incorporated the limitations that the Board had placed on the activity in the 1982 order. *See* 70 Federal Reserve Bulletin 121, 137 (1984).

[74] Neither real estate brokerage nor real estate management is an activity that is financial in nature. *See* 12 U.S.C. 1843 note; Public Law 111–8, sec. 624 (Mar. 11, 2009).

[75] 12 CFR 225.28(b)(2)(vii).

[76] *See* 62 FR 9290, 9305 (February 28, 1997).

[77] *Id.*

[78] *Id.*

[79] 12 U.S.C. 1843(k)(4)(F); 12 CFR 225.28(b)(3).

[80] *See* 62 FR 9290, 9306 (February 28, 1997) (''These requirements were developed in the course of litigation regarding the leasing activities of national banks, and were relied on by the courts in distinguishing bank leasing activities from general property rental and real estate development businesses. The requirement that a lease be nonoperating is also a statutory requirement limiting the high residual value leasing activities of national banks.'')

[81] 12 U.S.C. 1843(k)(4)(F); 12 CFR 225.28(b)(4).

Dodd-Frank Act, which provides that all revenues from or assets related to the ownership of an insured depository institution shall be considered to be financial.

• Trust Company Functions

The activities performed by a trust company (including activities of a fiduciary, agency, or custodial nature) that is not a bank for purposes of section 2(c) of the BHC Act were determined to be closely related to banking by the Board.[82]

• Financial and Investment Advisory Activities

Acting as an investment or financial advisor to any person was determined to be closely related to banking by the Board.[83] The activity includes, without limitation, serving as a registered investment adviser to a registered investment company, including sponsoring, organizing, and managing a closed-end investment company; furnishing general economic information and advice, general economic statistical forecasting services, and industry studies; providing advice in connection with mergers, acquisitions, divestitures, investments, joint ventures, leveraged buyouts, recapitalizations, capital structurings, financing transactions and similar transactions; and conducting financial feasibility studies; providing information, statistical forecasting, and advice with respect to any transaction in foreign exchange, swaps, and similar transactions, commodities, and any forward contract, option, future, option on a future, and similar instruments; providing educational courses and instructional materials to consumers on individual financial management matters; and providing tax-planning and tax-preparation services to any person.[84]

• Agency Transactional Services for Customer Investments

Providing agency transactional services, including providing securities brokerage services, acting as a riskless principal, providing private placement services, and acting as a futures commission merchant were determined to be closely related to banking by the Board.[85]

Regulation Y imposes conditions on the manner in which bank holding companies may conduct securities brokerage services, act as riskless principal, provide private placement services, and act as a futures commission merchant. For instance, bank holding companies providing securities brokerage services under this authority are limited to buying and selling securities solely as agent for the account of customers and may not conduct securities underwriting or dealing activities. Bank holding companies providing private placement services under this authority may not purchase or repurchase for their own account the securities being placed or hold in inventory unsold portions of issues of those securities. Bank holding companies acting as riskless principal under this authority are subject to conditions with respect to bank-ineligible securities.

Each of these conditions was intended to prevent a bank holding company from engaging in securities underwriting or dealing activities in connection with the activities of securities brokerage, private placement, or riskless principal, which were impermissible for bank holding companies under the Glass-Steagall Act at the time the activities were authorized.[86] The fact that a firm may retain some portion of shares in connection with, for example, private placement activities, does not affect or negate the financial nature of private placement activities. Moreover, as described elsewhere, securities underwriting and dealing activities were subsequently determined by statute to be financial activities. Thus, the appendix provides that the following activities are financial without the non-definitional conditions:

○ Providing securities brokerage services (including securities clearing and/or securities execution services on an exchange), whether alone or in combination with investment advisory services, and incidental activities (including related securities credit activities and custodial services).

○ Buying and selling in the secondary market all types of securities on the order of customers as a ''riskless principal'' in a transaction in which the company purchases (or sells) the security for its own account to offset a contemporaneous sale to (or purchase from) the customer.

○ Acting as agent for the private placement of securities in accordance with the requirements of the Securities Act of 1933 (1933 Act) and the rules of the Securities and Exchange Commission.

Under the Board's regulations, a bank holding company acting as a futures commission merchant must conduct the activity through a separately incorporated subsidiary, the contract must be traded on an exchange, and the parent bank holding company may not guarantee that subsidiary's liabilities. The appendix does not reflect these conditions, as they were imposed for the prudential purpose of limiting the transmission of risk from these activities to an insured depository affiliate or the parent bank holding company.[87]

The Board's regulations also contain a broad provision authorizing a bank holding company to provide ''transactional services for customers involving any derivative or foreign exchange transaction that a bank holding company is permitted to conduct for its own account.''[88] Specifically, the Board's Regulation Y describes the activity as ''[p]roviding to customers as agent transactional services with respect to swaps and similar transactions, any transaction described in paragraph (b)(8) of this section, any transaction that is permissible for a state member bank, and any other transaction involving a forward contract, option, futures, option on a futures or similar contract (whether traded on an exchange or not) relating to a commodity that is traded on an exchange.''[89] In the Second NPR, the Board proposed removing the requirement that agent transactional services on certain commodity derivatives transactions be provided only with respect to a commodity that is traded on an exchange (regardless of whether the contract being traded is traded on an exchange) because the limitation was imposed for safety and soundness reasons. In light of comments received, the Board has determined that

[82] 12 U.S.C. 1843(k)(4)(F); 12 CFR 225.28(b)(5).

[83] 12 U.S.C. 1843(k)(4)(F); 12 CFR 225.28(b)(6).

[84] *Id.*

[85] 12 U.S.C. 1843(k)(4)(F); 12 CFR 225.28(b)(7).

[86] *See* 62 FR 9290, 9307–9308 (February 28, 1997).

[87] *Id.* at 9309. (''The Board has determined that a * * * restriction that prohibits the parent bank holding company from guaranteeing or otherwise becoming liable for non-proprietary trades conducted by or through its FCM subsidiary * * * effectively addresses the Board's concern about a parent bank holding company's exposure to an exchange's or clearinghouse's loss sharing rules * * * [by protecting] the parent bank holding company from potential exposure from customer trades and open-ended contingent liability under loss sharing rules * * *'').

[88] *Id.* at 9310.

[89] 12 CFR 225.28(b)(7)(v). The 1997 rulemaking describes this financial activity as permitting a bank holding company to ''* * * act as a broker with respect to forward contracts based on a financial or nonfinancial commodity that also serves as the basis for an exchange-traded futures contract. This permits a bank holding company to act as agent in a forward contract that involves the same commodities and assessment of risk that underlay the permissible FCM activities of bank holding companies without extending this authority to forward contracts for the delayed sale of commercial products (such as automobiles, consumer products, etc.) or real estate.'' *See* 62 *FR* 9290, 9311 (February 28, 1997).

this condition, while serving a prudential role, also is part of the definition of the authorized activity because it prevents a bank holding company from engaging in the forward sale of commercial products. Because the condition distinguishes the financial activity of engaging in derivatives contracts from the commercial sale of assets, the final appendix includes this condition.

• Investment Transactions as Principal

Engaging in investment transactions as principal, including underwriting and dealing in government obligations and money market instruments, investing and trading as principal in foreign exchange and derivatives, and buying and selling bullion were determined to be closely related to banking by the Board.[90] Under the Board's regulations, bank holding companies engaged in underwriting and dealing in government obligations and money market instruments are subject to the same limitations as would be applicable if the activity were performed by member banks.[91] The appendix does not reflect this limitation because it was intended to prevent circumvention of the Glass-Steagall Act. This condition does not define the activity of engaging in investment transactions as principal and is therefore not relevant for determining whether the activity of underwriting and dealing in government obligations and money market instruments is financial for purposes of determining whether a firm is predominantly engaged in financial activities.[92]

Under the Board's regulations, engaging in derivatives transactions is a financial activity provided that the derivative contract is not a bank-ineligible security, and either the asset underlying the contract is a bank permissible asset or the contract contains conditions designed to limit the potential that physical settlement would occur.[93]

In the Second NPR, the Board proposed to remove these conditions in defining derivatives activities that are financial activities. Commenters expressed the view that the conditions requiring cash-settlement were necessary to distinguish between commercial activities involving physically settled derivatives contracts and the types of financial derivative activities conducted by financial companies.

The Board has considered these comments, as well as the Board's other precedents, in evaluating whether the conditions relating to cash-settlement and assignment or offset are an essential part of the definition of the financial activity of engaging in derivatives activities. These conditions were imposed by the Board originally to reduce the potential that bank holding companies would become involved in and bear the risks of physical possession, transport, storage, and delivery of commodities and to ensure that the commodity derivatives business of a bank holding company is largely limited to acting as a financial intermediary in the facilitation of transactions for customers who use or produce commodities or are otherwise exposed to commodity price risk as part of their regular business.[94] In certain instances, the Board has determined that engaging in physically-settling commodities, physical commodity trading, energy tolling, and energy management services, are activities that are complementary to the financial activity of engaging as principal in commodity derivatives transactions.[95] Under section 4(k) of the BHC Act, complementary activities are those that, although not necessarily financial in nature, are so meaningfully connected to financial activities that they complement those financial activities.

Based on this review, the Board has determined that these conditions, while serving an important prudential role, are also part of the definition of the authorized activity because they distinguish these derivatives activities from similar derivatives activities that are not conducted as a financial intermediary. Thus, the appendix includes, as a financial activity for purposes of Title I, engaging as principal in forward contracts, options, futures, options on futures, swaps, and similar contracts, whether traded on exchanges or not, based on any rate, price, financial asset (including gold, silver, platinum, palladium, copper, or any other metal), nonfinancial asset, or group of assets, other than a bank-ineligible security[96] if: (i) A state member bank is authorized to invest in the asset underlying the contract;[97] (ii) the contract requires cash settlement; (iii) the contract allows for assignment, termination, or offset prior to delivery or expiration, and the company makes every reasonable effort to avoid taking or making delivery of the asset underlying the contract, or receives and instantaneously transfers title to the underlying asset, by operation of contract and without taking or making physical delivery of the asset; or (iv) the contract does not allow for assignment, termination, or offset prior to delivery or expiration and is based on an asset for which futures contracts or options on futures contracts have been approved for trading on a U.S. contract market by the Commodity Futures Trading Commission, and the company makes every reasonable effort to avoid taking or making delivery of the asset underlying the contract, or receives and instantaneously transfers title to the underlying asset, by operation of contract and without taking or making physical delivery of the asset.

Similarly, engaging as principal in forward contracts, options, futures, options on futures, swaps, and similar contracts, whether traded on exchanges or not, based on an index of a rate, a price, or the value of any financial asset, nonfinancial asset, or group of assets, is a financial activity only if the contract requires cash settlement.

Investing and trading in foreign exchange is a financial activity under the Board's regulations.

The Board also received a comment in response to the Second NPR requesting that the Board clarify that derivatives transactions would not be considered ''financial'' with respect to a commercial manufacturer, producer, shipper, energy, or commodity firm when they are incidental or ancillary to a party's activities as such. Under the Dodd-Frank Act, whether an activity is ''financial'' is determined by the nature of the activity, rather than by what type of firm conducts the activity. Thus, the Board did not amend the appendix to the final rule in this manner.

[90] 12 U.S.C. 1843(k)(4)(F); 12 CFR 225.28(b)(8).

[91] 12 CFR 225.28(b)(8)(i).

[92] 62 FR 9290, 9311 (February 28, 1997).

[93] 12 CFR 225.28(b)(8)(ii)(B).

[94] *See* 68 FR 39807, 39808 (July 3, 2003).

[95] *See* Board letters regarding Bank of America Corporation (April 24, 2007), Credit Suisse Group (March 27, 2007), Fortis S.A./N.V. (September 29, 2006), and Wachovia Corporation (April 13, 2006); and Board orders regarding Royal Bank of Scotland Group plc, 94 Federal Reserve Bulletin C60 (2008), *Societe Generale,* 92 Federal Reserve Bulletin C113 (2006), *Deutsche Bank AG,* 91 Federal Reserve Bulletin C54 (2005), *JPMorgan Chase & Co.,* 91 Federal Reserve Bulletin C57 (2005); *Barclays Bank PLC,* 90 Federal Reserve Bulletin 511 (2004), *UBS AG,* 90 Federal Reserve Bulletin 215 (2004), and *Citigroup Inc.,* 89 Federal Reserve Bulletin 508 (2003).

[96] The Board's Regulation Y provides that a bank-ineligible security is any security that a state member bank is not permitted to underwrite or deal in under 12 U.S.C. 24 and 335.

[97] State member banks may own, for example, investment grade corporate debt securities, U.S. government and municipal securities, foreign exchange, and certain precious metals. *See* 68 FR 39807, 39808, note 2 (July 3, 2003).

• Management Consulting and Counseling Activities

The Board has authorized management consulting as a permissible activity under several different authorities, each of which are encompassed within the cross-references contained in section 4(k) of the BHC Act. Providing management consulting advice on any matter to unaffiliated depository institutions and on any financial, economic, accounting, or audit matter to any other company (''financial management consulting services'') was determined to be closely related to banking by the Board.[98] Under the Board's regulations, bank holding companies that engage in financial management consulting services also are permitted to provide management consulting services generally to any company *other than an unaffiliated depository institution, on any non-financial matter* (''non-financial management consulting services''), provided at least 70 percent of the bank holding company's total annual revenue derived from all management consulting services is derived from financial management consulting services. The revenue limitation on providing non-financial management consulting services was designed to limit the involvement of bank holding companies in the provision of management consulting services on non-financial matters to nondepository institutions. The limitations on the authority of bank holding companies to provide non-financial management consulting services does not change the nature of the permissible financial management consulting services done within those limits.

For purposes of applying the asset and revenue tests under Title I, assets and revenues derived from or associated with any management consulting services to a depository institution and any consulting on financial, economic, accounting, or audit matters to any company, will be considered financial. In addition, because a bank holding company may derive up to 30 percent of its total annual revenue from non-financial management consulting services and still be considered to be engaged in financial management consulting activities under the Board's regulations, for purposes of the applying the asset and revenue tests under Title I, up to 30 percent of a nonbank company's assets or revenues related to non-financial management consulting services will be included in the company's financial assets or revenues.

The Board's regulations also prohibit a bank holding company providing financial management consulting services from owning or controlling more than 5 percent of the voting securities of a client institution or from having a management interlock.[99] These conditions were intended to ensure that a bank holding company does not effectively exercise control over a client company with which it has a management consulting contract, thereby circumventing the prohibitions and notice requirements applicable to bank holding companies seeking to acquire a controlling interest in a company engaged in nonbanking activities, and to prevent conflicts of interest.[100] However, the Board believes that these conditions also serve a definitional role to distinguish management consulting from the actual conduct of the commercial activity in which a client firm is engaged.

The authorization for these activities overlaps with, and is largely subsumed under, the broader authority to engage in management consulting services that was determined to be usual in connection with banking abroad, described below. Therefore, a company that engages in management consulting activities in a manner that does not comply with the conditions described above will be considered to be engaged in a financial activity if its management consulting activities are captured by the broader authority.

Providing employee benefits consulting services to employee benefit, compensation and insurance plans, including designing plans, assisting in the implementation of plans, providing administrative services to plans, and developing employee communication programs for plans was determined to be closely related to banking by the Board.[101] Providing career counseling services also was determined to be closely related to banking by the Board,[102] subject to the condition that the services must be provided to a financial organization and individuals currently employed by, or recently displaced from, a financial organization; to individuals who are seeking employment at a financial organization; or to individuals currently employed in or who are seeking positions in the finance, accounting, and audit departments of any company. These conditions are essential to this activity's being considered financial, and thus, this activity is included in the appendix with these conditions.

• Courier Services and Printing and Selling MICR-encoded Items

The activity of providing courier services for: (i) Checks, commercial papers, documents, and written instruments (excluding currency or bearer-type negotiable instruments) that are exchanged among banks and financial institutions, and (ii) audit and accounting media of a banking or financial nature and other business records and documents used in processing such media was determined to be closely related to banking by the Board.[103]

The activity of printing and selling checks and related documents, including corporate image checks, cash tickets, voucher checks, deposit slips, savings withdrawal packages, and other forms that require Magnetic Ink Character Recognition encoding also was determined to be closely related to banking by the Board.[104]

• Insurance Agency and Underwriting

Certain insurance activities, including activities related to the provision of credit insurance and insurance in small towns, were determined to be closely related to banking by the Board.[105] Under the Board's regulations, bank holding companies may engage in these activities, subject to various conditions and limitations, which are reflected in the appendix. However, the authorization for these activities overlaps with, and is largely subsumed under, the general authority to engage in insurance underwriting and insurance agency activities discussed above. Therefore, a company that engages in insurance activities in a manner that does not comply with the conditions described above will be considered to be

[98] 12 U.S.C. 1843(k)(4)(F); 12 CFR 225.28(b)(9)(i). The Board's regulations provide that in conducting management consulting advice, bank holding companies are not authorized to perform tasks or operations or provide services to client institutions either on a daily or continuing basis, except as necessary to instruct the client institution on how to perform such services for itself. This restriction was designed to limit a bank holding company's activities to providing advice rather than other services that may involve impermissible activities for bank holding companies. For purposes of Title I, assets and revenues derived from providing management consulting services to a depository institution and any consulting on financial, economic, accounting, or audit matters to any company, will be considered financial regardless of other services the firm might provide. *See* 12 CFR 225.28(b)(9)(i), note 11.

[99] *See id. See also* 62 FR 9290, 9304, 9312 (February 28, 1997).

[100] *See* 62 FR 9290, 9304, 9312 (February 28, 1997).

[101] 12 U.S.C. 1843(k)(4)(F); 12 CFR 225.28(b)(9)(ii).

[102] 12 U.S.C. 1843(k)(4)(F); 12 CFR 225.28(b)(9)(iii).

[103] 12 U.S.C. 1843(k)(4)(F); 12 CFR 225.28(b)(10)(i).

[104] 12 U.S.C. 1843(k)(4)(F); 12 CFR 225.28(b)(10)(ii).

[105] 12 U.S.C. 1843(k)(4)(F); 12 CFR 225.28(b)(11).

engaged in a financial activity if its insurance activities are captured by the general authority.

• Community Development Activities

The activities of making debt and equity investments in corporations or projects that are designed primarily to promote community welfare, and providing advisory and related services for such programs was determined to be closely related to banking by the Board.[106]

• Money Orders, Savings Bonds, and Traveler's Checks

Issuing and selling money orders and similar consumer-type payment instruments, selling U.S. savings bonds, and issuing traveler's checks were determined to be closely related to banking by the Board.[107]

• Data Processing

Providing data processing services and related activities with respect to financial, banking, or economic data was determined to be closely related to banking by the Board.[108] Under the Board's regulations, a bank holding company's data processing activities must comply with the conditions that the hardware provided in connection with these services be offered only in conjunction with software related to the processing, storage, and transmission of financial, banking, or economic data, and all general purpose hardware provided with financial software not constitute more than 30 percent of the cost of any packaged offering.

The restrictions on providing hardware as part of providing financial data processing services were designed to limit the involvement of bank holding companies in the sale of data processing hardware, in particular, the sale of general purpose hardware. The limitations on the authority of bank holding companies to provide hardware as part of financial data processing do not change the nature of the permissible financial data processing done within those limits. For purposes of applying the asset and revenue tests under Title I, only that portion of a firm's data processing that involves providing financial data processing along with related hardware up to the limits imposed on bank holding companies would be considered financial activities. The provision of hardware or nonfinancial data processing beyond those limits would not disqualify the financial data processing revenues or assets, but also would not be considered financial activities.

• Mutual Fund Administrative Services

Providing administrative and other services to mutual funds was determined be closely related to banking by the Board.[109]

• Owning Shares of a Securities Exchange

Owning shares of a securities exchange was determined to be closely related to banking by the Board.[110]

• Certification Services

Acting as a certification authority for digital signatures and authenticating the identity of persons conducting financial and nonfinancial transactions was determined to be closely related to banking by the Board.[111]

• Providing Employment Histories

Providing employment histories to third parties for use in making credit decisions and to depository institutions and their affiliates for use in the ordinary course of business was determined to be closely related to banking by the Board.[112]

• Check-Cashing and Wire-Transmission Services

Providing check-cashing and wire-transmission services was determined to be closely related to banking by the Board.[113]

• Postage, Vehicle Registration, Public Transportation Services

The activities of providing notary-public services, selling postage stamps and postage-paid envelopes, providing vehicle registration services, and selling public-transportation tickets and tokens, when offered in connection with banking services, were determined to be closely related to banking by the Board.[114]

• Real Estate Title Abstracting

Engaging in real estate title abstracting was determined to be closely related to banking by the Board.[115]

iii. Financial Activities That are Usual in Connection With Banking or Other Financial Operations Abroad

Section 4(k) defines as a financial activity ''engaging, in the United States, in any activity that: (i) A bank holding company may engage in outside of the United States; and (ii) the Board has determined pursuant to section 4(c)(13) of the BHC Act to be usual in connection with the transaction of banking or other financial operations abroad.'' [116] These activities are described below.

• Management Consulting Services

As noted previously, the Board has authorized management consulting as a permissible activity under several different authorities contained in the cross-references in section 4(k) of the BHC Act. In addition to finding that management consulting services are closely related to banking for purposes of section 4(c)(8) of the BHC Act, described above, the Board also determined that providing management consulting services is usual in connection with the transaction of banking or other financial operations abroad under section 4(c)(13) of the BHC Act.[117] Under the Board's regulations, a bank holding company may provide management consulting services, ''including to any person with respect to nonfinancial matters, so long as the management consulting services are advisory and do not allow the financial holding company to control the person to which the services are provided.'' [118]

In the second NPR, the Board proposed to define this financial activity without regard to the condition that the bank holding company not control a client firm because this condition was imposed to prevent bank holding companies from circumventing the prohibitions and approval requirements in the BHC Act and to prevent conflicts of interest, as described previously. However, the Board believes that this condition also serves a definitional role to distinguish management consulting from the actual conduct of the activities in which a client firm is engaged, which may be commercial in nature. Therefore, the Board has restored this condition to the definition of management consulting activities that will be considered financial for purposes of Title I.

• Travel Agency

Operating a travel agency in connection with providing financial

[106] 12 U.S.C. 1843(k)(4)(F); 12 CFR 225.28(b)(12).
[107] 12 U.S.C. 1843(k)(4)(F); 12 CFR 225.28(b)(13).
[108] 12 U.S.C. 1843(k)(4)(F); 12 CFR 225.28(b)(14).
[109] 12 U.S.C. 1843(k)(4)(F); 12 CFR 225.86(a)(2)(i).
[110] 12 U.S.C. 1843(k)(4)(F); 12 CFR 225.86(a)(2)(ii).
[111] 12 U.S.C. 1843(k)(4)(F); 12 CFR 225.86(a)(2)(iii).
[112] 12 U.S.C. 1843(k)(4)(F); 12 CFR 225.86(a)(2)(iv).
[113] 12 U.S.C. 1843(k)(4)(F); 12 CFR 225.86(a)(2)(v).
[114] 12 U.S.C. 1843(k)(4)(F); 12 CFR 225.86(a)(2)(vi).
[115] 12 U.S.C. 1843(k)(4)(F); 12 CFR 225.86(a)(2)(vii).
[116] 12 U.S.C. 1843(k)(4)(G).
[117] 12 U.S.C. 1843(k)(4)(G); 12 CFR 225.86(b)(1).
[118] 12 CFR 225.86(b)(1).

services was determined to be usual in connection with the transaction of banking or other financial operations abroad.[119] This activity could be conducted in connection with any of the financial activities listed in this appendix, such as, for example, engaging in credit card activities.[120]

• Mutual Fund Activities

Organizing, sponsoring, and managing a mutual fund was determined to be usual in connection with the transaction of banking or other financial operations abroad.[121] This activity is in addition to, and in some ways includes, the financial activity of providing administrative services to mutual funds discussed above. Under the Board's regulations, bank holding companies are prohibited from exerting managerial control over the companies in which the mutual fund invests and must reduce their ownership to less than 25 percent of the equity of the mutual fund within one year of sponsoring the fund. These conditions do not define the essential nature of organizing, sponsoring, or managing a mutual fund. Rather, they were imposed to prevent circumvention of the investment restrictions in the BHC Act.[122] Therefore, they are not reflected in the appendix.

• Commercial Banking Activities

Engaging in commercial banking and other banking activities was determined to be usual in connection with the transaction of banking or other financial operations abroad.[123] Commercial banking activities include the ownership of a bank, as well as engaging in activities and making investments permissible for a bank.[124] The purchase of liquidity instruments, such as U.S. government securities, is an activity that is permissible for a bank. Some commenters had suggested that assets such as liquidity instruments not be included in a company's financial revenues or assets for purposes of determining whether the company is predominantly engaged in financial activities. However, investing in bank permissible investments is intrinsic to commercial banking. Therefore, a nonbank company's purchase of liquidity instruments would be included in the company's financial revenues and assets.

c. Implications for Bank Holding Companies

As noted in the Second NPR, the activities listed in the appendix would be defined as financial solely for purposes of Title I of the Dodd-Frank Act. The appendix is not intended to amend section 4(k) of the BHC Act for purposes of defining those activities that are permissible for financial holding companies or the manner in which bank holding companies and financial holding companies are permitted to conduct those activities.

d. Other Activities

As described above, section 4(k) of the BHC Act authorizes the Board, in consultation with the Secretary of the Treasury, to determine in the future that additional activities are ''financial in nature.'' [125] One commenter contended that the universe of financial activities that should be included when calculating either the revenue or asset test should be frozen as of the date on which the Dodd-Frank Act was passed and should not include additional activities that the Board, in consultation with the Secretary of the Treasury, determines in the future to be ''financial in nature.''

The Board has considered this comment and believes that the language of section 102 of the Dodd-Frank Act is best read as providing that any activities that are considered to be ''financial in nature'' at the time a company is considered under the asset or revenue test to determine whether such company is predominantly engaged in financial activities, should be included in such calculation.

Section 102 specifically provides that an activity that is ''financial in nature'' as defined in section 4(k) of the BHC Act, shall be considered to be a financial activity for purposes of determining whether a company is predominantly engaged in financial activities. The definition of financial activities under section 4(k) is not static, and, under the terms of section 4(k), may be expanded. In light of the evolving nature of financial markets and companies, the inclusion of all activities that are considered to be financial at the time the determination is made ensures that the definition of ''financial activities'' for purposes of the designation process accurately reflects that evolution. This interpretation also is consistent with the statutory process that requires the Council to revisit designation decisions at least annually. This provision of the statute contemplates that a company's status as a ''nonbank financial company'' would not remain static, but would be reevaluated at different times in the future. This requirement to revisit designation decisions indicates that Congress foresaw that the mix of financial and nonfinancial activities conducted by companies could change over time. A company's mix of financial and nonfinancial activities could change in the future for various reasons, including a determination by the Board and the Secretary of the Treasury, that additional activities should be considered to be financial in nature under section 4(k).

In addition, the Board believes that this interpretation is consistent with the Council's duties under section 112 of the Dodd-Frank Act, which include monitoring the financial services marketplace to identify potential threats to the financial stability of the United States and providing a forum for discussion and analysis of emerging market developments and financial regulatory issues. The Council's duties and authorities contemplate that the Council will stay abreast of the evolving nature of financial activities, markets, and companies. The inclusion of all activities that are considered to be financial at the time the determination is made helps ensure that the Council fulfills its statutory duties, authorities, and purposes, including its authority to consider any company that is predominantly engaged in financial activities that could pose a threat to U.S. financial stability for designation. The Board, as appropriate, will, on a case-by-case basis, provide assistance to companies in determining whether a particular activity is financial in nature for purposes of Title I.[126]

[119] 12 U.S.C. 1843(k)(4)(G); 12 CFR 225.86(b)(2).

[120] *See* 48 FR 56932, 56933 (December 27, 1983).

[121] 12 U.S.C. 1843(k)(4)(G); 12 CFR 225.86(b)(3).

[122] Furthermore, the Board's regulations governing a financial holding company's merchant banking activities authorizes the financial holding company to own all of the voting shares of a fund, but no more than 25 percent of the equity of the fund, which demonstrates that section 4(k) authorizes financial holding companies to control funds. The limitation on a financial holding company's equity interest in a fund was a prudential limitation imposed to limit the potential losses to which the financial holding company may be exposed.

[123] 12 CFR 211.10(a)(1).

[124] The Board's regulations implementing section 4(k) of the BHC Act do not include this activity because the regulations were intended to identify the activities that may be conducted using the post-transaction notice procedures. In the preamble to the final rule implementing section 4(k), the Board expressed the view that ''the GLB Act did not authorize a financial holding company to conduct commercial and other banking activities in the United States by using the post-transaction notice procedure.'' 66 FR 400, 405 (January 3, 2001). The fact that post-transaction notice procedures are not available for commercial or other banking activities does not impact the conclusion that engaging in commercial and other banking activities is a financial activity for purposes of determining whether a firm is predominantly engaged in financial activities under Title I.

[125] *See* 12 U.S.C. 1843(k)(1)–(k)(3).

[126] The First NPR proposed a formal procedure under which a company could request that the Board determine whether a particular activity is

3. Equity Investments in Unconsolidated Entities

The First NPR included two rules of construction governing the application of the two-year test to revenues and assets attributable to a company's minority equity investments in unconsolidated entities. Under the first proposed rule of construction, the Board proposed to attribute to a company all revenues derived from, and assets related to, the company's equity investment in any unconsolidated company that itself is predominantly engaged in financial activities.[127] This rule of construction would have required companies to determine whether 85 percent or more of an investee company's revenues or assets were attributable to financial activities for purposes of determining whether to treat revenues and assets related to unconsolidated minority investments as financial. Under the second rule of construction, the Board proposed to permit (but not require) a company to treat as nonfinancial the revenues and assets attributable to a limited amount of *de minimis* equity investments in unconsolidated companies without having to separately determine whether the investee company is itself predominantly engaged in financial activities.[128]

First Rule of Construction: Unconsolidated Investments

Several commenters asserted that a company's minority equity investments in an unconsolidated company should not be included in a company's financial revenues or assets when determining whether such company is predominantly engaged in financial activities unless the investment was made in connection with a merchant banking investment as defined in section 4(k) of the BHC Act or was made in a subsidiary of the company. Some commenters expressed the view that requiring a company to determine whether unconsolidated investee companies are themselves predominantly engaged in financial activities would be unduly burdensome.

In light of the comments, the Board has eliminated the requirement that a company determine whether an unconsolidated company in which it has made an investment is predominantly engaged in financial activities. Rather, the Board has amended the final rule to provide that an investment in an unconsolidated company will be presumed to be made in the course of conducting a financial activity set forth in section 4(k). In the Board's experience, this presumption is appropriate because most companies that derive a significant portion of revenue from, or have significant assets related to, investments in unconsolidated companies (such as hedge funds, private equity funds, or mutual funds) generally hold those investments for purposes of resale in connection with a bona fide merchant or investment banking activity as set forth in section 4(k)(4)(H), make those investments in connection with the activity of investing for others as defined in section 4(k)(4)(A), or invest in companies engaged in financial activities as provided for in section 4(k)(1). This presumption will reduce burden on companies by allowing them to determine whether they are predominantly engaged in financial activities without having to determine whether an unconsolidated company in which it has invested is itself predominantly engaged in financial activities.[129] In addition, this presumption will reduce burden on companies that are required to report their credit exposure to significant bank holding companies and significant nonbank financial companies under section 165(d) of the Dodd-Frank Act, which requires companies subject to this reporting obligation to identify companies that are predominantly engaged in financial activities, and thus, nonbank financial companies.

However, the Board recognizes that the presumption will not be appropriate in all instances, such as when a company holds an investment in a supplier in order to manage its supply chain more efficiently, to otherwise integrate various aspects of the company's business, or as a joint venture to engage in a business related to the company's primary business, among other possibilities. Accordingly, a company may rebut the presumption that an investment in a particular unconsolidated company is related to a financial activity by providing evidence to the Council, with respect to the definition of a nonbank financial company for purposes of Title I (other than with respect to the definition of a significant nonbank financial company), or the Board, with respect to the definition of a significant nonbank financial company, that the investment is not a merchant banking investment, an investment for others, an investment in a company engaged in activities that are financial in nature, or is not otherwise related to a financial activity. The Council or the Board, as appropriate, will consider this evidence on a case-by-case basis to determine whether the revenues derived from, or the assets related to, a company's investment in an unconsolidated company should be considered to be financial revenues or assets of the company.

The Board also has amended the first rule of construction to clarify that it would apply to a nonbank company's investment in an unconsolidated company, regardless of whether this investment would constitute a ''minority'' investment under applicable accounting standards. This amendment is intended to address circumstances in which an investor holds more than a majority of an investee company's voting shares but has granted substantive participating rights or similar rights to minority shareholders and, therefore, does not have a controlling financial interest under applicable accounting standards.

Second Rule of Construction: De Minimis Investments

As noted above, the first NPR contained a second rule of construction that would permit (but not require) a company to treat as nonfinancial the revenues and assets attributable to investments in unconsolidated companies representing less than five percent of any class of outstanding voting shares, and less than 25 percent of the total equity, of the unconsolidated company without having to separately determine whether those companies are themselves predominantly engaged in financial activities.[130] This rule of construction was subject to several conditions designed to limit the

financial in nature for purposes of Title I, which was substantially similar to the procedure outlined in § 225.88 of the Board's Regulation Y under which a financial holding company or other interested entity may request a determination from the Board that an activity is financial in nature or incidental to a financial activity. The final rule contemplates that the Board and Council, as appropriate, will help companies determine whether the company is predominantly engaged in financial activities. As part of this process, the Board expects to provide assistance to companies attempting to determine whether a particular activity is financial, as appropriate, consistent with the Board's interpretive authority under the BHC Act and its authority under section 102(a)(6) of the Dodd-Frank Act. Therefore, the Board has determined that it is unnecessary to include in the final rule a formal procedure under which a company may request that the Board determine whether a particular activity is financial in nature.

[127] *See* § 225.301(e)(1) of the First NPR.

[128] *See* § 225.301(e)(2) of the First NPR.

[129] Unless this presumption is rebutted, a nonbank company's investment income, including the company's proportionate share of earnings associated with an investment accounted for under the equity method, and dividend income from investments in unconsolidated companies will be included in the company's financial revenues for purposes of the revenue test.

[130] *See* § 225.301(e)(2) of the First NPR.

potential for these *de minimis* investments to substantially alter the financial character of the activities of a company.[131]

In light of the rebuttable presumption discussed above, which provides that the Board will presume that a company's investments in unconsolidated companies are financial as either a merchant banking investment under section 4(k)(4)(H), an investment made for others under section 4(k)(4)(A), or an investment in a company engaged in activities that are financial in nature under section 4(k)(1), and the company's ability to rebut the presumption in consultation with the Board, the second rule of construction is no longer necessary. The Council or the Board as appropriate, will, on a case-by-case basis, consider whether a particular investment is related to an activity that is financial in nature as defined in section 4(k), including investments representing less than five percent of any class of the unconsolidated investee company's outstanding voting shares, and less than 25 percent of the unconsolidated investee company's total equity.

4. Characterization of Internal Financial Activities and Certain Assets

Several commenters requested that the Board clarify whether revenues derived from, or assets related to, internal financial activities should be included as financial revenues or assets when determining whether a company is predominantly engaged in financial activities.

As the Board explained in the First NPR, the definition of financial activities includes all activities that have been, or may be, determined to be ''financial in nature'' under section 4(k) regardless of where the activity is conducted by a company or whether the company is conducting the activity on an internal or inter-affiliate basis or with a third-party. This view is consistent with the language of the Dodd-Frank Act. Section 102(a)(6) does not distinguish between financial activities conducted internally or those conducted with third parties. This is in sharp contrast to the specific terms of sections 113(c) and 167(b) of the Dodd-Frank Act, which provide that the Board may require a nonbank financial company to conduct its financial activities in an intermediate holding company ''other than'' internal financial activities, including internal treasury, investment, and employee benefit functions.[132] The absence of such an exclusion in section 102(a)(6) indicates that Congress intended that internal financial activities be included for purposes of determining whether a company is predominantly engaged in financial activities as defined in section 102(a)(6).

In addition, some commenters requested that the Board clarify that particular assets, such as cash, goodwill and other intangibles, and accounts receivable that relate to the company's financing a non-financial activity or product, are not included in a company's assets related to financial activities for purposes of determining whether the company is predominantly engaged in financial activities.

The Dodd-Frank Act compares assets related to financial activities to a firm's total assets. Cash on hand is not easily mapped to or necessarily used to fund a particular financial activity. Moreover, while a firm may be able to trace the generation of cash to a particular activity internally, the Dodd-Frank Act also contemplates that third parties be able to determine whether a firm is predominantly engaged in financial activities.[133] Third parties are not privy to the type of internal documentation that would allow them to assess whether cash is related to a particular financial activity. Consequently, the final rule excludes cash from a company's consolidated total assets and consolidated total financial assets for purposes of determining whether a company is predominantly engaged in financial activities under the asset test. However, inflows of cash generally may be attributed to particular activities for purposes of the revenue test in the Dodd-Frank Act using the company's cash flow statement. Thus, all revenues, including cash, that are derived from financial activities must be included in the revenue test.

Holdings of cash equivalents represent investments and are, therefore, related to the financial activity of making bank-permissible investments. Therefore, cash equivalents are assets related to a financial activity for purposes of the asset test.

Intangible assets generally may be attributed to a particular activity. Accordingly, the final rule treats each intangible asset in the same manner as the transaction or asset that gives rise to the intangible asset. An intangible asset is a financial asset of the company for purposes of the asset test only to the extent that it is related to the conduct of a financial activity. For example, mortgage servicing rights generate an intangible asset derived from an activity determined to be financial under section 4(k) of the BHC Act. On the other hand, goodwill, which is generally recognized as an intangible asset, is generated when a company makes an acquisition at a premium over the fair value of the asset acquired. The final rule allows exclusion of goodwill from the company's consolidated total assets and consolidated total financial assets for purposes of determining whether a company is predominantly engaged in financial activities under the asset test.

Accounts receivable may, in some cases, be related to the financial activity of extending credit, such as when the firm charges the customer interest over a term in exchange for the credit after a product or service is delivered. In other cases, a company's accounts receivable may simply reflect an agreement to accept payment from customers on a specified date for the company's goods and services. In those instances, the company may simply have provided its customers an accommodation to provide payment by a certain date with no credit terms such as interest. Because accounts receivable may in some cases reflect a company's extensions of credit, the Board has determined that it is most appropriate to treat accounts receivable as related to a financial activity unless a company rebuts this presumption by providing evidence to the Council, with respect to the definition of a nonbank financial company for purposes of Title I (other

[131] Specifically, this rule of construction provided that a company may treat revenues derived from, or assets related to, an equity investment by the company in an investee company as revenues or assets not derived from, or related to, activities that are financial in nature (regardless of the type of activities conducted by the other company), if (i) the company owns less than five percent of any class of outstanding voting shares, and less than 25 percent of the total equity, of the investee company; (ii) the financial statements of the investee company are not consolidated with those of the company under applicable accounting standards; (iii) the company's investment in the investee company is not held in connection with the conduct of any financial activity (such as, for example, investment advisory activities or merchant banking investment activities) by the company or any of its subsidiaries; (iv) the investee company is not a bank, bank holding company, broker-dealer, insurance company, or other regulated financial institution; and (v) the aggregate amount of revenues or assets treated as nonfinancial under the rule of construction in any year does not exceed five percent of the company's annual gross financial revenues or consolidated total financial assets of the company.

[132] 12 U.S.C. 5323(c) and 5367(b). *See also* section 626 of the Dodd-Frank Act; 12 U.S.C. 1467b.

[133] As previously discussed, section 165(d)(2) of the Dodd-Frank Act requires nonbank financial companies supervised by the Board and bank holding companies and foreign banks treated as bank holding companies with $50 billion or more in assets to report their credit exposure to significant nonbank financial companies and bank holding companies, which requires companies subject to this reporting obligation be identify those companies that are predominantly engaged in financial activities, and thus, nonbank financial companies.

than with respect to the definition of a significant nonbank financial company), or the Board, with respect to the definition of a significant nonbank financial company, that the receivable is not related to extending credit. As is the case with respect to the other presumptions adopted by the Board in this rulemaking, this presumption will help companies determine whether they are predominantly engaged in financial activities and will reduce burden on companies that are required to report their credit exposure to significant nonbank financial companies under section 165(d) of the Dodd-Frank. A company may rebut this presumption by providing evidence to the Council or the Board that the receivable is not related to extending credit, and the evidence will be considered on a case-by-case basis to determine whether the receivable should be considered to be related to a financial activity.

As noted previously, the Board recognizes that determining whether and the extent to which particular revenues or assets are related to financial activities may be a complex endeavor, and the Council and the Board, as appropriate, will assist companies on a case-by-case basis that require assistance in determining whether the company is predominantly engaged in financial activities.

5. Appropriate Accounting Standards

Under the two-year test set forth in the First NPR, the amount of a company's financial revenues and financial assets would be calculated as a percentage of the company's consolidated annual gross revenues and consolidated total assets, respectively, as determined under and in accordance with (1) U.S. generally accepted accounting principles (GAAP), if the company uses GAAP in the ordinary course of its business in preparing its consolidated financial statements, (2) International Financial Reporting Standards (IFRS), if the company uses IFRS in the ordinary course of its business in preparing its consolidated financial statements, or (3) such other accounting standards that the Board determines are appropriate.[134] The final rule retains this provision, but provides that the Council, with respect to the definition of a nonbank financial company for purposes of Title I of the Dodd-Frank Act (other than with respect to the definition of a significant nonbank financial company), or the Board, with respect to the definition of a significant nonbank financial company, may determine that an accounting standard other than GAAP or IFRS is appropriate on a case-by-case basis.[135] In determining whether an accounting standard other than GAAP or IFRS is appropriate, the Board expects that the Council and the Board would consider various factors, including whether the accounting standard is used by the company in the ordinary course of its business in preparing its consolidated financial statements. Reliance on an accounting standard that the company uses in the ordinary course reduces the potential for companies to arbitrage the 85 percent financial test by changing the accounting standards used for these purposes.

As the Board explained in the First NPR, the rule allows companies to use their consolidated, year-end financial statements (prepared in accordance with the accounting standards discussed above) as the basis for determining their annual gross revenues and consolidated assets for purposes of the two-year test. This methodology is likely to provide a transparent, accurate, and comparable basis for determining such amounts across companies and, thus, should facilitate the ability of a company, the Council, and the Board to determine whether a company is a nonbank financial company for purposes of Title I of the Dodd-Frank Act. Moreover, allowing companies to use the year-end consolidated financial statements that they already prepare for financial reporting or other purposes should help reduce potential burden.

6. Timing of Determination

The final rule provides the Council and the Board with the flexibility, in appropriate circumstances, to consider whether a company meets the statute's 85 percent financial revenue or asset test based on the full range of information that may be available concerning the company's activities and assets (including information obtained from other Federal or state financial supervisors or agencies) at any time rather than only as reflected in the company's year-end consolidated financial statements.[136]

For example, the Board notes that the mix of a company's revenues or assets, as well as the risks the company could pose to the U.S. financial system, may change significantly and quickly as a result of various types of transactions or actions, such as a merger, consolidation, acquisition, establishment of a new business line, or the initiation of a new activity. Moreover, these transactions and actions may occur at any time during a company's fiscal year and, accordingly, the effects of the transactions or actions may not be reflected in the year-end consolidated financial statements of the company for several months.

Section 242.3(a)(3) of the final rule would allow the Council, with respect to the definition of a nonbank financial company for purposes of Title I (other than with respect to the definition of a significant nonbank financial company), or the Board, with respect to the definition of a significant nonbank financial company, to promptly consider the effect of changes in the nature or mix of a company's activities as a result of such a transaction or action. The Board expects that the Council and the Board would conduct such a case-by-case review of whether a company is predominantly financial only when justified by the circumstances. In addition, this authority would enable the Council and the Board, in appropriate circumstances, to determine whether a company that does not prepare consolidated financial statements is predominantly engaged in financial activities through consultation with the company.

B. Significant Nonbank Financial Company and Significant Bank Holding Company

As discussed above, the Dodd-Frank Act requires the Board to define the terms ''significant nonbank financial company'' and ''significant bank holding company'' by rule.[137]

[134] For example, one commenter requested that the Board clarify that statutory accounting principles (SAP) would qualify as an appropriate accounting standard for calculating a firm's financial revenues and financial assets. The commenter indicated that some insurance companies, for example, prepare their financial statements in accordance with SAP and are not required by insurance law or regulation to prepare financial statements in accordance with GAAP. A company could request that the Council or the Board, as appropriate, permit the company to use an alternative accounting standard, such as SAP. A company seeking to use an alternative accounting standard for purposes of determining whether it is predominantly engaged in financial activities should provide information to the Council or the Board that describes why the proposed alternative accounting standard likely would ensure a presentation of the company's consolidated revenues and assets in a manner that reliably allows a determination of whether the firm meets or does not meet the statutory test for a nonbank financial company.

[135] *See* § 242.2(a)(3) of the Final Rule.

[136] *See* § 242.3(a)(3) of the Final Rule.

[137] *See* sections 102(a)(7) of the Dodd-Frank Act; 12 U.S.C. 5311(a)(7). These terms are used in two places in the Dodd-Frank Act. First, under section 113, the Council must consider the relationships of a nonbank financial company with significant nonbank financial companies and significant bank holding companies in determining whether the nonbank financial company should be subjected to supervision by the Federal Reserve (12 U.S.C.

Continued

The First NPR defined a ''significant nonbank financial company'' to mean (i) any nonbank financial company supervised by the Board; and (ii) any other nonbank financial company that had $50 billion or more in total consolidated assets as of the end of its most recently completed fiscal year. The final rule retains this definition. The final rule defines a ''significant bank holding company,'' as ''any bank holding company or company that is, or is treated in the United States as, a bank holding company, that had $50 billion or more in total consolidated assets as of the end of the most recently completed calendar year'' as reported by the bank holding company or company that is, or is treated in the United States as, a bank holding company on the appropriate Federal Reserve form.

Several commenters provided suggestions regarding the $50 billion asset threshold established in the proposed definitions of ''significant nonbank financial company'' and ''significant bank holding company.'' One commenter requested that the Board adjust the threshold for inflation, and another commenter suggested that the Board define ''significant nonbank financial company'' to include only those firms that the Council has designated for Board supervision under section 113 and eliminate that portion of the definition based on the $50 billion asset threshold.

The Board designed the threshold to provide a transparent standard that other companies and the Council may use in meeting their respective statutory obligations to consider the relationships of companies with ''significant'' nonbank financial companies and bank holding companies. The requirement that firms calculate their exposure to significant nonbank financial companies and bank holding companies based on widely-used and transparent standards likely will reduce the burden imposed on the Council and those firms that are required to calculate their exposure to significant entities.

In establishing this threshold, the Board considered its supervisory experience with bank holding companies. The Board also considered the fact that Congress established $50 billion in total consolidated assets as the threshold (without an inflation adjustment) at which bank holding companies should be subject to enhanced prudential supervision without any special determination by the Council that the bank holding company's failure would pose a threat to financial stability. The Board also notes that a company that meets the definition of either a ''significant'' nonbank financial company or bank holding company would not be subject to any additional supervision or regulation by virtue of that definition.

For these reasons, the Board has concluded that there is a sufficient basis for adopting the $50 billion threshold for purposes of defining ''significant'' nonbank financial companies and bank holding companies. The Board has determined not to include an inflation adjustment provision in the final rule. An inflation adjustment would add complexity and burden to the definition without any significant benefit in more accurately defining the relevant terms. However, the Board may consider amending the $50 billion threshold in the future if the Board determines that such reconsideration is appropriate.

Several commenters suggested that the Board exclude certain assets from the calculation of a nonbank financial company's ''total consolidated assets,'' despite the consolidation of such assets on the company's balance sheet under GAAP or other appropriate accounting standards. For instance, several commenters requested that the Board exclude managed assets and investment fund assets when calculating the total assets of the asset manager or fund adviser in situations in which applicable accounting standards provide for the consolidation of such assets on the balance sheets of the asset manager and the fund adviser, respectively. The commenters contended that exclusion of such assets was appropriate, because such assets are not the at-risk assets of the manager or adviser.

Another commenter requested that the calculation of the $50 billion threshold with respect to asset managers and fund advisers exclude capitalized goodwill and other intangibles that are not financial assets that are impacted by temporary market movements, and for which the clients have no direct or indirect ownership interest. Commenters also suggested that separate investment funds managed by the same investment adviser not be consolidated when measuring total consolidated assets of the adviser. With respect to the definition of a ''significant bank holding company,'' one commenter suggested that the $50 billion asset calculation should include only the U.S.-based assets of the bank holding company or foreign bank treated as a bank holding company, rather than the company's worldwide consolidated assets.

The Board has considered these comments and has retained the requirements in the final rule that the calculation of ''total consolidated assets'' of a nonbank financial company include a company's worldwide consolidated assets as determined in accordance with GAAP, IFRS, or other appropriate accounting standards. The Board believes that the determination of total consolidated assets based on applicable accounting principles provides a reliable, uniform (across a given accounting framework), and simple approach that is most readily applied by the Council, the Board, and affected companies with the least burden. Any other approach would require the Council, the Board, and affected companies to obtain information from the ''significant'' firms and make adjustments to the reported assets of the firm, which would be burdensome and potentially unreliable.

The Board also has retained the proposed definition of a ''significant bank holding company'' as any bank holding company or foreign bank or company that is treated as a bank holding company that had $50 billion or more in total consolidated assets as of the end of the most recently completed calendar year (as reported by the bank holding company or foreign bank on the appropriate Federal Reserve form), based on the bank holding company's consolidated worldwide assets. Using worldwide consolidated assets measures the significance of a bank holding company and, as above, imposes the least burden on the Council, the Board, and the relevant entities.

Several commenters requested that the Board highlight the distinction between ''significant'' nonbank financial companies and nonbank financial companies that are designated by the Council for supervision by the Board under section 113 of the Dodd-Frank Act. Qualifying as a significant nonbank financial company is *not* tantamount to a determination by the Council to subject a nonbank financial company to heightened prudential supervision by the Board under section 113 of the Dodd-Frank Act. A company that is considered to be a significant bank holding company or a significant nonbank financial company does not become subject to any additional supervision or regulation by virtue of that definition.

One commenter expressed concern that the proposed rule neither established a procedure under which a company could determine whether it were a ''significant'' nonbank financial

5323(a)(2), (b)(2)). Second, under section 165(d)(2), nonbank financial companies and bank holding companies with $50 billion or more of total consolidated assets must file credit reports that include their exposures to significant nonbank financial companies and significant bank holding companies (12 U.S.C. 5365(d)(2)).

company, nor imposed a requirement that a company calculate or publish its classification as significant. Like the proposed rule, the final rule does not impose a requirement that a company determine whether it meets the definition of either a ''significant'' nonbank financial company or bank holding company, because a company is not required to report its status as ''significant'' to the Board. Rather, the determination regarding a company's status as ''significant'' as provided in the final rule is intended to be self-executing and based on readily available financial statements.

One commenter suggested that the Board consider defining ''significant'' companies differently for purposes of sections 113 and 165(d)(2) of the Act. As the Board discussed in the proposed rule, while the Board alone is responsible for defining ''significant'' nonbank financial companies and bank holding companies for purposes of section 113, the Board and the FDIC are jointly responsible for developing rules to implement the credit exposure reporting requirements under section 165(d)(2), under which nonbank financial companies supervised by the Board and bank holding companies and foreign banks treated as bank holding companies with $50 billion or more in assets must report their credit exposure to ''significant'' nonbank financial companies and bank holding companies. The Board and the FDIC sought comment on a joint proposed rule on April 12, 2011, to implement the provisions of section 165(d), including the credit exposure reporting requirements.[138] The joint proposed rule adopted the same definitions of the terms ''significant'' nonbank financial company and bank holding company as proposed by the Board in the First NPR, and as adopted in this final rulemaking.

Several commenters requested that the final rule address circumstances under which a determination that a company is a significant nonbank financial company or bank holding company would be treated by the Board as confidential under the Freedom of Information Act. Other commenters requested that the Board refrain from publishing a list of significant nonbank financial companies and bank holding companies.

Because neither the statute nor the final rule requires a significant nonbank financial company or bank holding company to report its status as ''significant'' to the Board, the statute and the final rule also do not require the Board to make a determination regarding whether a nonbank financial company or bank holding company is ''significant.'' Moreover, because the Dodd-Frank Act imposes requirements on certain firms that deal with ''significant'' nonbank financial companies and bank holding companies, and not on the nonbank financial companies or bank holding companies themselves, it is important that firms that must identify significant companies can do so without impediments on the availability of information.

III. Administrative Law Matters

A. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Ch. 3506; 5 CFR part 1320 Appendix A.1), the Board reviewed this final rule under the authority delegated to the Board by the Office of Management and Budget (''OMB''). The final rule contains no collections of information under the PRA. *See* 44 U.S.C. 3502(3). Accordingly, there is no paperwork burden associated with the final rule.[139] One commenter asserted that the Board's analysis of the proposed rule under the Paperwork Reduction Act was insufficient because the proposal did not contain any notice or request for comment regarding any collection of information to determine whether a company would be considered to be a ''significant nonbank financial company.'' However, neither the statute nor the final rule requires: (i) A ''significant'' nonbank financial company or bank holding company to report its status as ''significant'' to the Board, or (ii) the Board to make such a determination regarding a nonbank financial company or bank holding company. For these reasons, the Board does not anticipate conducting or sponsoring the collection of any information related to the Board's establishment of the definitions of ''significant'' nonbank financial company'' and ''significant'' bank holding company in this final rule.

B. Regulatory Flexibility Act

In accordance with Section 4(a) of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.* (''RFA''), the Board must publish a final regulatory flexibility analysis with this rulemaking. The RFA requires an agency either to provide a final regulatory flexibility analysis with a final rule for which a general notice of proposed rulemaking is required or to certify that the final rule will not have a significant economic impact on a substantial number of small entities. Based on its analysis and for the reasons stated below, the Board believes that the final rule will not have a significant economic impact on a substantial number of small entities. Nevertheless, the Board is publishing a final regulatory flexibility analysis.

In accordance with sections 102(b) and 102(a)(7) of the Dodd-Frank Act, the Board is adopting Regulation PP (12 CFR 242 *et seq.*) to establish the criteria for determining if a company is ''predominantly engaged in financial activities'' and to define the terms ''significant nonbank financial company'' and ''significant bank holding company.''[140] The reasons and justifications for the rule are described in the **SUPPLEMENTARY INFORMATION**. As discussed in the **SUPPLEMENTARY INFORMATION**, the criteria and definitions that are established by the rule are relevant to the authority of the Council to require that a nonbank financial company become subject to consolidated prudential supervision by the Board, because material financial distress at the company, or the nature, scope, size, scale, concentration, interconnectedness, or mix of the company's activities, could pose a threat to the financial stability of the United States.

Although asset size may not be the determinative factor of whether a company may pose systemic risks, it is an important consideration.[141] Under regulations issued by the Small Business Administration (''SBA''), firms within the ''Finance and Insurance'' sector are considered ''small'' if they have asset sizes that vary from $7 million or less in assets to $175 million or less in assets.[142] The Board believes that the Finance and Insurance sector constitutes a reasonable universe of firms for these purposes because such firms generally engage in activities that are financial in nature. A financial firm that is at or below these size thresholds is not likely to be designated by the Council under section 113 of the Dodd-

[138] *See* 76 FR 22648 (2011). The Board and FDIC issued a final rule implementing several of the provisions of section 165(d) on November 1, 2011. The agencies did not finalize the credit exposure reporting requirement at that time. *See* 76 FR 67323, 67327 (November 1, 2011).

[139] As described previously, the First NPR proposed a formal procedure under which a company could request in writing a determination from the Board as to whether a particular activity is financial in nature. However, the Board believes that it is unnecessary to include in the final rule a formal procedure under which a company may request in writing that the Board determine whether a particular activity is financial in nature. The elimination of this formal procedure from the final rule has eliminated all potential paperwork burden associated with this final rule.

[140] 12 U.S.C. 5311(a)(7) and (b).

[141] *See* 77 FR 21637 (April 11, 2012).

[142] 13 CFR 121.201.

Frank Act because material financial distress at such a firm, or the nature, scope, size, scale, concentration, interconnectedness, or mix of its activities, is not likely to pose a threat to the financial stability of the United States.[143]

In addition, as described in the Supplementary Information, the Board also has taken several steps to reduce the potential burden of the rule on all companies that may be affected by the rule. These steps include allowing companies to use their consolidated, year-end financial statements prepared in accordance with GAAP or IFRS as the basis for determining whether they are predominantly engaged in financial activities, and establishing a rule of construction governing the application of the two-year test to revenues and assets attributable to a company's unconsolidated investments. In addition, the presumptions adopted by the Board in connection with determining whether a company is predominantly engaged in financial activities will reduce burden on companies attempting to determine whether they are predominantly engaged in financial activities and on companies that are required to report their credit exposure to significant bank holding companies and significant nonbank financial companies under section 165(d) of the Dodd-Frank Act.

One commenter expressed the view that although it is unlikely that companies with less than $175 million in assets would be designated by the Council, in the event that a money market mutual fund were designated, small businesses, municipal entities, and small non-profit organizations that invest in the fund would face higher costs. Furthermore, the commenter argued that a money market mutual fund that was designated would likely be less active in the short term debt markets, which would lead to less liquid and more expensive markets for small municipal and governmental entities that issue commercial paper. For these reasons, the commenter asserted that the RFA requires the Board to perform a cost-benefit analysis of its proposed rules because the RFA applies even in those instances in which a regulation does not directly apply to an entity, but directly affects it.[144]

The question of whether the RFA requires consideration of the indirect application of a rule has been considered by the courts, which have held that the RFA only requires an analysis of how a rule affects small entities that would be directly subject to its requirements.[145] As described above, the final rule establishes the criteria for determining if a company is ''predominantly engaged in financial activities'' and defines the terms ''significant nonbank financial company'' and ''significant bank holding company,'' which are relevant to the authority of the Council to designate a nonbank financial company for consolidated prudential supervision by the Board, because the nonbank financial company could pose a threat to the financial stability of the United States. The final rule does not impose requirements directly on any entity.[146] Moreover, as the Board noted in the First NPR, it is extremely unlikely that a company with less than $175 million in assets would be designated. As such, the Board believes that the final rule will not have a significant economic impact on a substantial number of small entities.

The same commenter also asserted that the Board is required to perform a cost benefit analysis under Executive Order 13579. The Executive Order cited by the commenter does not mandate that independent agencies such as the Board perform a cost benefit analysis of their regulations. However, the Board takes seriously the importance of evaluating the burdens imposed by its rulemaking efforts. For example, the Board seeks to adopt final rules that faithfully reflect the statutory provisions and Congressional intent while minimizing regulatory burden. In addition, the Board provides an analysis of the costs to small entities of its rules consistent with the RFA and computes the anticipated cost of paperwork for affected entities consistent with the Paperwork Reduction Act in its rulemaking. As described above, the Board conducted a final regulatory flexibility analysis and an analysis under the PRA in connection with this rulemaking.

List of Subjects in 12 CFR Part 242

Administrative practice and procedure, Holding companies, Nonbank financial companies.

Authority and Issuance

For the reasons stated in the preamble, the Board adds new Part 242 to Chapter II of Title 12 as follows:

PART 242—DEFINITIONS RELATING TO TITLE I OF THE DODD–FRANK ACT (REGULATION PP)

Sec.
242.1 Authority and purpose.
242.2 Definitions.
242.3 Nonbank companies ''predominantly engaged'' in financial activities.
242.4 Significant nonbank financial companies and significant bank holding companies.
Appendix A to Part 242—Financial Activities for Purposes of Title I of the Dodd-Frank Act

Authority: 12 U.S.C. 5311.

§ 242.1 Authority and purpose.

(a) *Authority.* This part is issued by the Board pursuant to sections 102(a)(7) and (b) of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act) (12 U.S.C. 5311(a)(7) and (b)).

(b) *Purpose.* (1) This part establishes the criteria for determining if a company

[143] The terms ''significant nonbank financial company'' and ''significant bank holding company'' also are used in the credit exposure reporting provisions of section 165(d) of the Dodd-Frank Act, which apply to bank holding companies and foreign banks that are treated as a bank holding company that have $50 billion or more in assets (as well as nonbank financial companies supervised by the Board). Bank holding companies and foreign banks subject to these credit exposure reporting requirements substantially exceed the $175 million asset threshold at which a banking entity is considered ''small'' under regulations issued by the SBA.

[144] The commenter cited to *Aeronautical Repair Station Ass'n, Inc.* v. *FAA,* 494 F.3d 161, 177 (D.C. Cir. 2007). In that case, the FAA regulation at issue required employees who performed certain functions ''directly or by contract (including by subcontract at any tier)'' to be subject to drug and alcohol testing. The commenter stated that the ''court rejected arguments that an RFA analysis was unnecessary because contractors of air carriers were not 'directly regulated' and were not the 'targets' of the regulation. The commenter asserted that the court held that contractors were 'subject to the proposed regulation' for purposes of the RFA even though the regulation was 'immediately addressed' to the air carriers, because the regulations applied to employees of the contractors, just as it applied to employees of the air carriers. The contractors were 'directly affected and therefore regulated' within the meaning of the RFA.''

[145] *See Mid-Tex Elec. Coop* v. *FERC,* 773 F.2d 327 (D.C. Cir. 1985) and *American Trucking Ass'ns* v. *EPA,* 175 F.3d 1027, 1044 (D.C. Cir 1999), *aff'd in part and rev'd in part on other grounds, Whitman* v. *American Trucking Ass'ns,* 531 I/S/ 457 (2001). In *Mid-Tex,* the court rejected the argument that ''the RFA is intended to apply to all rules that affect small entities, whether the small entities are directly regulated or not,'' and held that the RFA requires agencies to consider the ''economic impact'' of a regulation on ''a substantial number of small entities *that are subject to the requirements''* of the regulation. *See* 773 F.2d at 342 (emphasis added). The court further stated that ''Congress did not intend to require that every agency consider every indirect effect that any regulation might have on small businesses in any stratum of the national economy.'' *See id.* at 343. The court in *Aeronautical Repair Station,* the case cited by the commenter, distinguished *Mid-Tex* and its progeny from the facts in that case, in which the regulations at issue ''expressly require[d] that the employees of contractors and subcontractors be tested'' for drug and alcohol use. *See* 494 F.3d at 177. For this reason, the court in *Aeronautical Repair Station* found that the rule at issue ''*impose[d] responsibilities directly on the contractors and subcontractors* and they [we]re therefore parties affected by and regulated by it.'' *See id.* (emphasis added).

[146] 12 U.S.C. 5311(a)(7) and (b).

is ''predominantly engaged in financial activities'' as required under section 102(b) of the Dodd-Frank Act (12 U.S.C. 5311(b)) for purposes of Title I of the Dodd-Frank Act.

(2) This part defines the terms ''significant nonbank financial company'' and ''significant bank holding company'' as provided in section 102(a)(6) of the Dodd-Frank Act for purposes of—

(i) Section 113 of the Dodd-Frank Act (12 U.S.C. 5323) relating to the designation of nonbank financial companies by the Financial Stability Oversight Council (Council) for supervision by the Board; and

(ii) Section 165(d)(2) of the Dodd-Frank Act (12 U.S.C. 5365(d)(2)) relating to the credit exposure reports required to be filed by—

(A) A nonbank financial company supervised by the Board; and

(B) A bank holding company or foreign bank subject to the Bank Holding Company Act (BHC Act) (12 U.S.C. 1841 *et seq.*) that has $50 billion or more in total consolidated assets.

§ 242.2 Definitions.

For purposes of this part, the following definitions shall apply:

Applicable accounting standards.—The term ''applicable accounting standards'' with respect to a company means:

(1) U.S. generally accepted accounting principles (GAAP), if the company uses GAAP in the ordinary course of its business in preparing its consolidated financial statements;

(2) International Financial Reporting Standards (IFRS), if the company uses IFRS in the ordinary course of its business in preparing its consolidated financial statements, or

(3) Such other accounting standards that the Council, with respect to the definition of a nonbank financial company for purposes of Title I of the Dodd-Frank Act (other than with respect to the definition of a significant nonbank financial company), or the Board, with respect to the definition of a significant nonbank financial company, determines are appropriate on a case-by-case basis.

Foreign nonbank financial company.—The term ''foreign nonbank financial company'' means a company (other than a company that is, or is treated in the United States, as a bank holding company) that is—

(1) Incorporated or organized in a country other than the United States; and

(2) Predominantly engaged in (including through a branch in the United States) financial activities as defined in § 242.3 of this part.

Nonbank financial company.—The term ''nonbank financial company'' means a U.S. nonbank financial company and a foreign nonbank financial company.

Nonbank financial company supervised by the Board.—The term ''nonbank financial company supervised by the Board'' means a nonbank financial company or other company that the Council has determined under section 113 of the Dodd-Frank Act (12 U.S.C. 5323) should be supervised by the Board and for which such determination is still in effect.

State.—The term ''State'' includes any State, commonwealth, territory, or possession of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, and the United States Virgin Islands.

U.S. nonbank financial company.—The term ''U.S. nonbank financial company'' means a company that—

(1) Is incorporated or organized under the laws of the United States or any State;

(2) Is predominantly engaged in financial activities as defined in § 242.3 of this part; and

(3) Is not—

(i) A bank holding company;

(ii) A Farm Credit System institution chartered and subject to the provisions of the Farm Credit Act of 1971 (12 U.S.C. 2001 *et seq.*);

(iii) A national securities exchange (or parent thereof), clearing agency (or parent thereof, unless the parent is a bank holding company), security-based swap execution facility, or security-based swap data repository that, in each case, is registered with the Securities and Exchange Commission as such; or

(iv) A board of trade designated as a contract market (or parent thereof), a derivatives clearing organization (or parent thereof, unless the parent is a bank holding company), a swap execution facility, or a swap data repository that, in each case, is registered with the Commodity Futures Trading Commission as such.

§ 242.3 Nonbank companies ''predominantly engaged'' in financial activities.

(a) *In general.* A company is ''predominantly engaged in financial activities'' for purposes of this section if—

(1) The consolidated annual gross financial revenues of the company in either of its two most recently completed fiscal years represent 85 percent or more of the company's consolidated annual gross revenues (as determined in accordance with applicable accounting standards) in that fiscal year;

(2) The consolidated total financial assets of the company as of the end of either of its two most recently completed fiscal years represent 85 percent or more of the company's consolidated total assets (as determined in accordance with applicable accounting standards) as of the end of that fiscal year; or

(3) The Council, with respect to the definition of a nonbank financial company for purposes of Title I of the Dodd-Frank Act (other than with respect to the definition of a significant nonbank financial company), or the Board, with respect to the definition of a significant nonbank financial company, determines, based on all the facts and circumstances, that—

(i) The consolidated annual gross financial revenues of the company represent 85 percent or more of the company's consolidated annual gross revenues; or

(ii) The consolidated total financial assets of the company represent 85 percent or more of the company's consolidated total assets.

(b) *Consolidated annual gross financial revenues.* For purposes of this section, the ''consolidated annual gross financial revenues'' of a company means that portion of the consolidated annual gross revenues of the company (as determined in accordance with applicable accounting standards) that are derived, directly or indirectly, by the company or any of its subsidiaries from—

(1) Activities that are financial in nature; or

(2) The ownership, control, or activities of an insured depository institution or any subsidiary of an insured depository institution.

(c) *Consolidated total financial assets.* For purposes of this section, the ''consolidated total financial assets'' of a company means that portion of the consolidated total assets of the company (as determined in accordance with applicable accounting standards) that are related to—

(1) Activities that are financial in nature; or

(2) The ownership, control, or activities of an insured depository institution or any subsidiary of an insured depository institution.

(d) *Activities that are financial in nature*—(1) *In general.* For purposes of determining whether a company is predominantly engaged in financial activities under this section, activities that are financial in nature are set forth in the appendix to this part. Nothing in

this part limits the authority of the Board under any other provision of law or regulation to modify the activities determined to be financial in nature for purposes of this section or for purposes of the BHC Act or to provide interpretations of section 4(k) of the BHC Act.

(2) *Effect of other authority.* Any activity described in the appendix is financial in nature for purposes of this part regardless of whether—

(i) A bank holding company (including a financial holding company or a company that is, or is treated in the United States as, a bank holding company) may be authorized to engage in the activity, or own or control shares of a company engaged in such activity, under any other provisions of the BHC Act or other Federal law including, but not limited to, section 4(a)(2), section 4(c)(5), section 4(c)(6), section 4(c)(7), section 4(c)(9), or section 4(c)(13) of the BHC Act (12 U.S.C. 1843(a)(2), (c)(5), (c)(6), (c)(7), (c)(9), or (c)(13)) and the Board's implementing regulations; or

(ii) Other provisions of Federal or state law or regulations prohibit, restrict, or otherwise place conditions on the conduct of the activity by a bank holding company (including a financial holding company or a company that is, or is treated in the United States, as a bank holding company) or bank holding companies generally.

(e) *Rules of construction.* For purposes of determining whether a company is predominantly engaged in financial activities under this section—

(1) *Unconsolidated investments.* (i) Unless otherwise determined by the Council or the Board in accordance with paragraph (e)(1)(ii) of this section, revenues derived from, and assets related to, an investment by the company in an entity whose financial statements are not consolidated with those of the company are presumed to be financial in nature.

(ii) A company may seek to rebut the presumption described in paragraph (e)(1)(i) of this section by providing evidence to the Council, with respect to the definition of a nonbank financial company for purposes of Title I of the Dodd-Frank Act (other than with respect to the definition of a significant nonbank financial company), or the Board, with respect to the definition of a significant nonbank financial company, that the shares or ownership interests are not held in connection with a bona fide merchant or investment banking activity, are not held in connection with the activity of investing for others, do not represent an investment in an entity engaged in activities that are financial in nature as defined in the appendix, or are not otherwise related to a financial activity.

(2) *Accounts receivable.* (i) Unless otherwise determined by the Council or the Board in accordance with paragraph (e)(2)(ii) of this section, an account receivable is presumed to be an asset related to the financial activity of extending credit.

(ii) A company may seek to rebut the presumption described in paragraph (e)(2)(i) of this section by providing evidence to the Council, with respect to the definition of a nonbank financial company for purposes of Title I of the Dodd-Frank Act (other than with respect to the definition of a significant nonbank financial company), or the Board, with respect to the definition of a significant nonbank financial company, that the account receivable is not related to a financial activity.

(3) *Goodwill.* Goodwill is excluded from a company's consolidated total assets and consolidated total financial assets.

(4) *Cash and cash equivalents.* (i) Cash is excluded from a company's consolidated total assets and consolidated total financial assets.

(ii) Cash equivalents are assets related to a financial activity.

(5) *Intangible assets.* Intangible assets are treated in the same manner as the transaction or asset that gives rise to the intangible asset.

§ 242.4 Significant nonbank financial companies and significant bank holding companies.

For purposes of Title I of the Dodd-Frank Act, the following definitions shall apply:

(a) *Significant nonbank financial company.* A ''significant nonbank financial company'' means—

(1) Any nonbank financial company supervised by the Board; and

(2) Any other nonbank financial company that had $50 billion or more in total consolidated assets (as determined in accordance with applicable accounting standards) as of the end of its most recently completed fiscal year.

(b) *Significant bank holding company.* A ''significant bank holding company'' means any bank holding company or company that is, or is treated in the United States as, a bank holding company, that had $50 billion or more in total consolidated assets as of the end of the most recently completed calendar year, as reported on either the Federal Reserve's FR Y–9C (Consolidated Financial Statement for Bank Holding Companies), or any successor form thereto, or the Federal Reserve's Form FR Y–7Q (Capital and Asset Report for Foreign Banking Organizations), or any successor form thereto.

Appendix A to Part 242—Financial Activities for Purposes of Title I of the Dodd-Frank Act

(a) Lending, exchanging, transferring, investing for others, or safeguarding money or securities.

(b) Insuring, guaranteeing, or indemnifying against loss, harm, damage, illness, disability, or death, or providing and issuing annuities, and acting as principal, agent, or broker for purposes of the foregoing, in any state.

(c) Providing financial, investment, or economic advisory services, including advising an investment company (as defined in section 3 of the Investment Company Act of 1940).

(d) Issuing or selling instruments representing interests in pools of assets permissible for a bank to hold directly.

(e) Underwriting, dealing in, or making a market in securities.

(f) Engaging in any activity that the Board has determined to be so closely related to banking or managing or controlling banks as to be a proper incident thereto, which include—

(1) *Extending credit and servicing loans.* Making, acquiring, brokering, or servicing loans or other extensions of credit (including factoring, issuing letters of credit and accepting drafts) for the company's account or for the account of others.

(2) *Activities related to extending credit.* Any activity usual in connection with making, acquiring, brokering or servicing loans or other extensions of credit, including the following activities:

(i) *Real estate and personal property appraising.* Performing appraisals of real estate and tangible and intangible personal property, including securities.

(ii) *Arranging commercial real estate equity financing.* Acting as intermediary for the financing of commercial or industrial income-producing real estate by arranging for the transfer of the title, control, and risk of such a real estate project to one or more investors.

(iii) *Check-guaranty services.* Authorizing a subscribing merchant to accept personal checks tendered by the merchant's customers in payment for goods and services, and purchasing from the merchant validly authorized checks that are subsequently dishonored.

(iv) *Collection agency services.* Collecting overdue accounts receivable, either retail or commercial.

(v) *Credit bureau services.* Maintaining information related to the credit history of consumers and providing the information to a credit grantor who is considering a borrower's application for credit or who has extended credit to the borrower.

(vi) *Asset management, servicing, and collection activities.* Engaging under contract with a third party in asset management, servicing, and collection [1] of assets of a type

[1] Asset management services include acting as agent in the liquidation or sale of loans and collateral for loans, including real estate and other assets acquired through foreclosure or in satisfaction of debts previously contracted.

that an insured depository institution may originate and own.

(vii) *Acquiring debt in default.* Acquiring debt that is in default at the time of acquisition.

(viii) *Real estate settlement servicing.* Providing real estate settlement services.[2]

(3) *Leasing personal or real property.* Leasing personal or real property or acting as agent, broker, or adviser in leasing such property if:

(i) The lease is on a nonoperating basis;[3]

(ii) The initial term of the lease is at least 90 days; and

(iii) In the case of leases involving real property:

(A) At the inception of the initial lease, the effect of the transaction will yield a return that will compensate the lessor for not less than the lessor's full investment in the property plus the estimated total cost of financing the property over the term of the lease from rental payments, estimated tax benefits, and the estimated residual value of the property at the expiration of the initial lease; and

(B) The estimated residual value of property for purposes of paragraph (f)(3)(iii)(A) of this section shall not exceed 25 percent of the acquisition cost of the property to the lessor.

(4) *Operating nonbank depository institutions.*

(i) *Industrial banking.* Owning, controlling, or operating an industrial bank, Morris Plan bank, or industrial loan company that is not a bank for purposes of the BHC Act.

(ii) *Operating savings associations.* Owning, controlling, or operating a savings association.

(5) *Trust company functions.* Performing functions or activities that may be performed by a trust company (including activities of a fiduciary, agency, or custodial nature), in the manner authorized by federal or state law that is not a bank for purposes of section 2(c) of the Bank Holding Company Act.

(6) *Financial and investment advisory activities.* Acting as investment or financial advisor to any person, including (without, in any way, limiting the foregoing):

(i) Serving as investment adviser (as defined in section 2(a)(20) of the Investment Company Act of 1940, 15 U.S.C. 80a–2(a)(20)), to an investment company registered under that act, including sponsoring, organizing, and managing a closed-end investment company;

(ii) Furnishing general economic information and advice, general economic statistical forecasting services, and industry studies;

(iii) Providing advice in connection with mergers, acquisitions, divestitures, investments, joint ventures, leveraged buyouts, recapitalizations, capital structurings, financing transactions and similar transactions, and conducting financial feasibility studies;[4]

(iv) Providing information, statistical forecasting, and advice with respect to any transaction in foreign exchange, swaps, and similar transactions, commodities, and any forward contract, option, future, option on a future, and similar instruments;

(v) Providing educational courses, and instructional materials to consumers on individual financial management matters; and

(vi) Providing tax-planning and tax-preparation services to any person.

(7) *Agency transactional services for customer investments.*

(i) *Securities brokerage.* Providing securities brokerage services (including securities clearing and/or securities execution services on an exchange), whether alone or in combination with investment advisory services, and incidental activities (including related securities credit activities and custodial services).

(ii) *Riskless principal transactions.* Buying and selling in the secondary market all types of securities on the order of customers as a ''riskless principal'' to the extent of engaging in a transaction in which the company, after receiving an order to buy (or sell) a security from a customer, purchases (or sells) the security for its own account to offset a contemporaneous sale to (or purchase from) the customer.

(iii) *Private placement services.* Acting as agent for the private placement of securities in accordance with the requirements of the Securities Act of 1933 (1933 Act) and the rules of the Securities and Exchange Commission.

(iv) *Futures commission merchant.* Acting as a futures commission merchant for unaffiliated persons in the execution, clearance, or execution and clearance of any futures contract and option on a futures contract.

(v) *Other transactional services.* Providing to customers as agent transactional services with respect to swaps and similar transactions, any transaction described in paragraph (f)(8) of this appendix, any transaction that is permissible for a state member bank, and any other transaction involving a forward contract, option, futures, option on a futures or similar contract (whether traded on an exchange or not) relating to a commodity that is traded on an exchange.

(8) *Investment transactions as principal.*

(i) *Underwriting and dealing in government obligations and money market instruments.* Underwriting and dealing in obligations of the United States, general obligations of states and their political subdivisions, and other obligations that state member banks of the Federal Reserve System may be authorized to underwrite and deal in under 12 U.S.C. 24 and 335, including banker's acceptances and certificates of deposit.

(ii) *Investing and trading activities.* Engaging as principal in:

(A) Foreign exchange;

(B) Forward contracts, options, futures, options on futures, swaps, and similar contracts, whether traded on exchanges or not, based on any rate, price, financial asset (including gold, silver, platinum, palladium, copper, or any other metal), nonfinancial asset, or group of assets, other than a bank-ineligible security,[5] if—

(*1*) A state member bank is authorized to invest in the asset underlying the contract;

(*2*) The contract requires cash settlement;

(*3*) The contract allows for assignment, termination, or offset prior to delivery or expiration, and the company—

(*i*) Makes every reasonable effort to avoid taking or making delivery of the asset underlying the contract; or

(*ii*) Receives and instantaneously transfers title to the underlying asset, by operation of contract and without taking or making physical delivery of the asset; or

(*4*) The contract does not allow for assignment, termination, or offset prior to delivery or expiration and is based on an asset for which futures contracts or options on futures contracts have been approved for trading on a U.S. contract market by the Commodity Futures Trading Commission, and the company—

(*i*) Makes every reasonable effort to avoid taking or making delivery of the asset underlying the contract; or

(*ii*) Receives and instantaneously transfers title to the underlying asset, by operation of contract and without taking or making physical delivery of the asset.

(C) Forward contracts, options,[6] futures, options on futures, swaps, and similar contracts, whether traded on exchanges or not, based on an index of a rate, a price, or the value of any financial asset, nonfinancial asset, or group of assets, if the contract requires cash settlement.

(iii) *Buying and selling bullion, and related activities.* Buying, selling and storing bars, rounds, bullion, and coins of gold, silver, platinum, palladium, copper, and any other metal for the company's own account and the account of others, and providing incidental

[2] For purposes of this section, real estate settlement services do not include providing title insurance as principal, agent, or broker.

[3] The requirement that the lease is on a nonoperating basis means that the company does not, directly or indirectly, engage in operating, servicing, maintaining, or repairing leased property during the lease term. For purposes of the leasing of automobiles, the requirement that the lease is on a nonoperating basis means that the company does not, directly or indirectly: (1) Provide servicing, repair, or maintenance of the leased vehicle during the lease term; (2) purchase parts and accessories in bulk or for an individual vehicle after the lessee has taken delivery of the vehicle; (3) provide the loan of an automobile during servicing of the leased vehicle; (4) purchase insurance for the lessee; or (5) provide for the renewal of the vehicle's license merely as a service to the lessee where the lessee could renew the license without authorization from the lessor.

[4] Feasibility studies do not include assisting management with the planning or marketing for a given project or providing general operational or management advice.

[5] A bank-ineligible security is any security that a state member bank is not permitted to underwrite or deal in under 12 U.S.C. 24 and 335.

[6] This reference does not include acting as a dealer in options based on indices of bank-ineligible securities when the options are traded on securities exchanges. These options are securities for purposes of the federal securities laws and bank-ineligible securities for purposes of section 20 of the Glass-Steagall Act, 12 U.S.C. 337. Similarly, this reference does not include acting as a dealer in any other instrument that is a bank-ineligible security for purposes of section 20. Bank holding companies that deal in these instruments must do so in accordance with the Board's orders on dealing in bank-ineligible securities.

services such as arranging for storage, safe custody, assaying, and shipment.

(9) *Management consulting and counseling activities.*

(i) *Management consulting.*

(A) Providing management consulting advice:[7]

(*1*) On any matter to unaffiliated depository institutions, including commercial banks, savings and loan associations, savings banks, credit unions, industrial banks, Morris Plan banks, cooperative banks, industrial loan companies, trust companies, and branches or agencies of foreign banks;

(*2*) On any financial, economic, accounting, or audit matter to any other company.

(B) Revenues derived from, or assets related to, a company's management consulting activities under this subparagraph will not be considered to be financial if the company:

(*1*) Owns or controls, directly or indirectly, more than 5 percent of the voting securities of the client institution; or

(*2*) Allows a management official, as defined in 12 CFR 212.2(h), of the company or any of its affiliates to serve as a management official of the client institution, except where such interlocking relationship is permitted pursuant to an exemption permitted by the Board.

(C) Up to 30 percent of a nonbank company's assets or revenues related to management consulting services provided to customers not described in paragraph (f)(9)(i)(A)(*1*) or regarding matters not described in paragraph (f)(9)(i)(A)(*2*) of this appendix will be included in the company's financial assets or revenues.

(ii) *Employee benefits consulting services.* Providing consulting services to employee benefit, compensation and insurance plans, including designing plans, assisting in the implementation of plans, providing administrative services to plans, and developing employee communication programs for plans.

(iii) *Career counseling services.* Providing career counseling services to:

(A) A financial organization[8] and individuals currently employed by, or recently displaced from, a financial organization;

(B) Individuals who are seeking employment at a financial organization; and

(C) Individuals who are currently employed in or who seek positions in the finance, accounting, and audit departments of any company.

(10) *Support services.*

(i) *Courier services.* Providing courier services for:

(A) Checks, commercial papers, documents, and written instruments (excluding currency or bearer-type negotiable instruments) that are exchanged among banks and financial institutions; and

(B) Audit and accounting media of a banking or financial nature and other business records and documents used in processing such media.[9]

(ii) *Printing and selling MICR-encoded items.* Printing and selling checks and related documents, including corporate image checks, cash tickets, voucher checks, deposit slips, savings withdrawal packages, and other forms that require Magnetic Ink Character Recognition (MICR) encoding.

(11) *Insurance agency and underwriting.*

(i) *Credit insurance.* Acting as principal, agent, or broker for insurance (including home mortgage redemption insurance) that is:

(A) Directly related to an extension of credit by the company or any of its subsidiaries; and

(B) Limited to ensuring the repayment of the outstanding balance due on the extension of credit[10] in the event of the death, disability, or involuntary unemployment of the debtor.

(ii) *Finance company subsidiary.* Acting as agent or broker for insurance directly related to an extension of credit by a finance company[11] that is a subsidiary of a company, if:

(A) The insurance is limited to ensuring repayment of the outstanding balance on such extension of credit in the event of loss or damage to any property used as collateral for the extension of credit; and

(B) The extension of credit is not more than $10,000, or $25,000 if it is to finance the purchase of a residential manufactured home[12] and the credit is secured by the home; and

(C) The applicant commits to notify borrowers in writing that:

(*1*) They are not required to purchase such insurance from the applicant;

(*2*) Such insurance does not insure any interest of the borrower in the collateral; and

(*3*) The applicant will accept more comprehensive property insurance in place of such single-interest insurance.

(iii) *Insurance in small towns.* Engaging in any insurance agency activity in a place where the company or a subsidiary has a lending office and that:

(A) Has a population not exceeding 5,000 (as shown in the preceding decennial census); or

(B) Has inadequate insurance agency facilities, as determined by the Board, after notice and opportunity for hearing.

(iv) *Insurance-agency activities conducted on May 1, 1982.* Engaging in any specific insurance-agency activity[13] if the company, or subsidiary conducting the specific activity, conducted such activity on May 1, 1982, or received Board approval to conduct such activity on or before May 1, 1982.[14] Revenues derived from, or assets related to, a company's specific insurance agency activity under this clause will be considered financial only if the company:

(A) Engages in such specific insurance agency activity only at locations:

(*1*) In the state in which the company has its principal place of business (as defined in 12 U.S.C. 1842(d));

(*2*) In any state or states immediately adjacent to such state; and

(*3*) In any state in which the specific insurance-agency activity was conducted (or was approved to be conducted) by such company or subsidiary thereof or by any other subsidiary of such company on May 1, 1982; and

(B) Provides other insurance coverages that may become available after May 1, 1982, so long as those coverages insure against the types of risks as (or are otherwise functionally equivalent to) coverages sold or approved to be sold on May 1, 1982, by the company or subsidiary.

(v) *Supervision of retail insurance agents.* Supervising on behalf of insurance underwriters the activities of retail insurance agents who sell:

(A) Fidelity insurance and property and casualty insurance on the real and personal property used in the operations of the company or its subsidiaries; and

(B) Group insurance that protects the employees of the company or its subsidiaries.

(vi) *Small companies.* Engaging in any insurance-agency activity if the company has total consolidated assets of $50 million or less. Revenues derived from, or assets related to, a company's insurance-agency activities under this paragraph will be considered financial only if the company does not engage in the sale of life insurance or annuities except as provided in paragraphs (f)(11) (i) and (iii) of this appendix, and does not continue to engage in insurance-agency activities pursuant to this provision more than 90 days after the end of the quarterly reporting period in which total assets of the

[7] In performing this activity, companies are not authorized to perform tasks or operations or provide services to client institutions either on a daily or continuing basis, except as necessary to instruct the client institution on how to perform such services for itself. *See also* the Board's interpretation of bank management consulting advice (12 CFR 225.131).

[8] Financial organization refers to insured depository institution holding companies and their subsidiaries, other than nonbanking affiliates of diversified savings and loan holding companies that engage in activities not permissible under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1842(c)(8)).

[9] See also the Board's interpretation on courier activities (12 CFR 225.129), which sets forth conditions for company entry into the activity.

[10] Extension of credit includes direct loans to borrowers, loans purchased from other lenders, and leases of real or personal property so long as the leases are nonoperating and full-payout leases that meet the requirements of paragraph (f)(3) of this appendix.

[11] Finance company includes all non-deposit-taking financial institutions that engage in a significant degree of consumer lending (excluding lending secured by first mortgages) and all financial institutions specifically defined by individual states as finance companies and that engage in a significant degree of consumer lending.

[12] These limitations increase at the end of each calendar year, beginning with 1982, by the percentage increase in the Consumer Price Index for Urban Wage Earners and Clerical Workers published by the Bureau of Labor Statistics.

[13] Nothing contained in this provision precludes a subsidiary that is authorized to engage in a specific insurance-agency activity under this clause from continuing to engage in the particular activity after merger with an affiliate, if the merger is for legitimate business purposes.

[14] For the purposes of this paragraph, activities engaged in on May 1, 1982, include activities carried on subsequently as the result of an application to engage in such activities pending before the Board on May 1, 1982, and approved subsequently by the Board or as the result of the acquisition by such company pursuant to a binding written contract entered into on or before May 1, 1982, of another company engaged in such activities at the time of the acquisition.

company and its subsidiaries exceed $50 million.

(vii) *Insurance-agency activities conducted before 1971.* Engaging in any insurance-agency activity performed at any location in the United States directly or indirectly by a company that was engaged in insurance-agency activities prior to January 1, 1971, as a consequence of approval by the Board prior to January 1, 1971.

(12) *Community development activities.*

(i) *Financing and investment activities.* Making equity and debt investments in corporations or projects designed primarily to promote community welfare, such as the economic rehabilitation and development of low-income areas by providing housing, services, or jobs for residents.

(ii) *Advisory activities.* Providing advisory and related services for programs designed primarily to promote community welfare.

(13) *Money orders, savings bonds, and traveler's checks.* The issuance and sale at retail of money orders and similar consumer-type payment instruments; the sale of U.S. savings bonds; and the issuance and sale of traveler's checks.

(14) *Data processing.*

(i) Providing data processing, data storage and data transmission services, facilities (including data processing, data storage and data transmission hardware, software, documentation, or operating personnel), databases, advice, and access to such services, facilities, or data-bases by any technological means, if the data to be processed, stored or furnished are financial, banking or economic.

(ii) Up to 30 percent of a nonbank company's assets or revenues related to providing general purpose hardware in connection with providing data processing products or services described in paragraph (f)(14)(i) of this appendix will be included in the company's financial assets or revenues.

(15) *Administrative services.* Providing administrative and other services to mutual funds.

(16) *Securities exchange.* Owning shares of a securities exchange.

(17) *Certification authority.* Acting as a certification authority for digital signatures and authenticating the identity of persons conducting financial and nonfinancial transactions.

(18) *Employment histories.* Providing employment histories to third parties for use in making credit decisions and to depository institutions and their affiliates for use in the ordinary course of business.

(19) *Check cashing and wire transmission.* Check cashing and wire transmission services.

(20) *Services offered in connection with banking services.* In connection with offering banking services, providing notary public services, selling postage stamps and postage-paid envelopes, providing vehicle registration services, and selling public transportation tickets and tokens.

(21) *Real estate title abstracting.*

(g) Engaging, in the United States, in any activity that a bank holding company may engage in outside of the United States; and the Board has determined, under regulations prescribed or interpretations issued pursuant to section 4(c)(13) of the BHC Act (12 U.S.C. 1843(c)(13)) to be usual in connection with the transaction of banking or other financial operations abroad. Those activities include—

(1) Providing management consulting services, including to any person with respect to nonfinancial matters, so long as the management consulting services are advisory and do not allow the company to control the person to which the services are provided.

(2) Operating a travel agency in connection with financial services.

(3) Organizing, sponsoring, and managing a mutual fund.

(4) Commercial banking and other banking activities.

(h) Directly, or indirectly acquiring or controlling, whether as principal, on behalf of 1 or more entities, or otherwise, shares, assets, or ownership interests (including debt or equity securities, partnership interests, trust certificates, or other instruments representing ownership) of a company or other entity, whether or not constituting control of such company or entity, engaged in any activity not financial in nature as defined in this appendix if:

(1) Such shares, assets, or ownership interests are acquired and held as part of a bona fide underwriting or merchant or investment banking activity, including investment activities engaged in for the purpose of appreciation and ultimate resale or disposition of the investment;

(2) Such shares, assets, or ownership interests are held for a period of time to enable the sale or disposition thereof on a reasonable basis consistent with the financial viability of the activities described in paragraph (h)(1) of this appendix; and

(3) During the period such shares, assets, or ownership interests are held, the company does not routinely manage or operate such company or entity except as may be necessary or required to obtain a reasonable return on investment upon resale or disposition.

(i) Directly or indirectly acquiring or controlling, whether as principal, on behalf of 1 or more entities, or otherwise, shares, assets, or ownership interests (including debt or equity securities, partnership interests, trust certificates or other instruments representing ownership) of a company or other entity, whether or not constituting control of such company or entity, engaged in any activity not financial in nature as defined in this appendix if—

(1) Such shares, assets, or ownership interests are acquired and held by an insurance company that is predominantly engaged in underwriting life, accident and health, or property and casualty insurance (other than credit-related insurance) or providing and issuing annuities;

(2) Such shares, assets, or ownership interests represent an investment made in the ordinary course of business of such insurance company in accordance with relevant state law governing such investments; and

(3) During the period such shares, assets, or ownership interests are held, the company does not routinely manage or operate such company except as may be necessary or required to obtain a reasonable return on investment.

(j) Lending, exchanging, transferring, investing for others, or safeguarding financial assets other than money or securities.

(k) Providing any device or other instrumentality for transferring money or other financial assets.

(l) Arranging, effecting, or facilitating financial transactions for the account of third parties.

By order of the Board of Governors of the Federal Reserve System, March 29, 2013.

Robert deV. Frierson,

Secretary of the Board.

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