



Federal Register

10-22-09

Vol. 74 No. 203

Thursday

Oct. 22, 2009

Pages 54429-54742



The **FEDERAL REGISTER** (ISSN 0097-6326) is published daily, Monday through Friday, except official holidays, by the Office of the Federal Register, National Archives and Records Administration, Washington, DC 20408, under the Federal Register Act (44 U.S.C. Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). The Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 is the exclusive distributor of the official edition. Periodicals postage is paid at Washington, DC.

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WHY: To provide the public with access to information necessary to research Federal agency regulations which directly affect them. There will be no discussion of specific agency regulations.

WHEN: Tuesday, November 20, 2009
9 a.m.-12:30 p.m.

WHERE: Office of the Federal Register
Conference Room, Suite 700
800 North Capitol Street, NW.
Washington, DC 20002

RESERVATIONS: (202) 741-6008



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Presidential Determination No. 2010–02 of October 16, 2009**The President****Provision of U.S. Drug Interdiction Assistance to the Government of Brazil****Memorandum for the Secretary of State [and] the Secretary of Defense**

Pursuant to the authority vested in me by section 1012 of the National Defense Authorization Act for Fiscal Year 1995, as amended (22 U.S.C. 2291–4), I hereby certify, with respect to Brazil, that (1) interdiction of aircraft reasonably suspected to be primarily engaged in illicit drug trafficking in that country's airspace is necessary because of the extraordinary threat posed by illicit drug trafficking to the national security of that country; and (2) that country has appropriate procedures in place to protect against innocent loss of life in the air and on the ground in connection with such interdiction, which shall at a minimum include effective means to identify and warn an aircraft before the use of force is directed against the aircraft.

The Secretary of State is authorized and directed to publish this determination in the *Federal Register* and to notify the Congress of this determination.



THE WHITE HOUSE,
Washington, October 16, 2009

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

Animal and Plant Health Inspection Service

7 CFR Part 301

[Docket No. APHIS-2009-0023]

RIN 0579-AC96

Citrus Canker; Movement of Fruit From Quarantined Areas

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the citrus canker regulations to modify the conditions under which fruit may be moved interstate from a quarantined area. We are eliminating the requirement that each lot of finished fruit be inspected at the packinghouse and found to be free of visible symptoms of citrus canker and removing the current prohibition on the movement of fruit from a quarantined area to commercial citrus-producing States. We are continuing to require fruit moved interstate from a quarantined area to be treated with an approved disinfectant and to be packed in a commercial packinghouse that operates under a compliance agreement. These changes will relieve some restrictions on the interstate movement of fresh citrus fruit from quarantined areas while maintaining conditions that will prevent the artificial spread of citrus canker.

EFFECTIVE DATE: October 22, 2009.

FOR FURTHER INFORMATION CONTACT: Mr. Stephen Poe, Senior Operations Officer, Emergency and Domestic Programs, Plant Protection and Quarantine, APHIS, 4700 River Road Unit 137, Riverdale, MD 20737-1231; (301) 734-4387.

SUPPLEMENTARY INFORMATION:

Background

Citrus canker is a plant disease caused by the bacterium *Xanthomonas citri* subsp. *citri* (referred to below as Xcc) that affects plants and plant parts, including fresh fruit, of citrus and citrus relatives (Family Rutaceae). Citrus canker can cause defoliation and other serious damage to the leaves and twigs of susceptible plants. It can also cause lesions on the fruit of infected plants, which render the fruit unmarketable, and cause infected fruit to drop from the trees before reaching maturity. The A (Asiatic) strain of citrus canker can infect susceptible plants rapidly and lead to extensive economic losses in commercial citrus-producing areas. Citrus canker is only known to be present in the United States in the State of Florida.

The regulations to prevent the interstate spread of citrus canker are contained in "Subpart—Citrus Canker" (7 CFR 301.75-1 through 301.75-14, referred to below as the regulations). The regulations restrict the interstate movement of regulated articles from and through areas quarantined because of citrus canker and provide, among other things, conditions under which regulated fruit may be moved into, through, and from quarantined areas for packing.

On June 30, 2009, we published in the **Federal Register** (74 FR 31201-31209, Docket No. APHIS-2009-0023) a proposal¹ to amend the regulations to modify the conditions under which fruit may be moved interstate from a quarantined area. We proposed to eliminate the requirement that each lot of finished fruit be inspected at the packinghouse and found to be free of visible symptoms of citrus canker and to remove the current prohibition on the movement of fruit from a quarantined area to American Samoa, Arizona, California, Guam, Hawaii, Louisiana, Commonwealth of the Northern Mariana Islands, Puerto Rico, Texas, and the U.S. Virgin Islands. (These are the commercial citrus-producing areas listed in § 301.75-5; we refer to them in this document as commercial citrus-producing States.)

We proposed to continue to require fruit moved interstate from a

quarantined area to be treated with an approved disinfectant and to be packed in a commercial packinghouse that operates under a compliance agreement. We proposed these changes to relieve some restrictions on the interstate movement of fresh citrus fruit from quarantined areas while maintaining conditions that would prevent the artificial spread of citrus canker.

We solicited comments concerning our proposal for 60 days ending August 31, 2009. We received 34 comments by that date. They were from citrus producers, citrus packers, industry organizations, researchers, and representatives of State and foreign governments. Twenty-three commenters supported the proposed rule. Two of these commenters also directly addressed issues raised in the remaining comments, which are discussed below by topic.

Selection of an Option for Mitigating the Risk Associated With the Interstate Movement of Regulated Fruit From a Quarantined Area

In a final rule² effective and published in the **Federal Register** on November 19, 2007 (72 FR 65172-65204, Docket No. APHIS-2007-0022), we amended the regulations to establish new conditions for the interstate movement of regulated fruit from an area quarantined for citrus canker. That final rule eliminated a requirement that the groves in which fruit to be moved interstate is produced be inspected and found free of citrus canker. Instead, we added the packinghouse inspection requirement mentioned earlier. We retained the other requirements that had been in the regulations, including the requirement that the fruit be treated with a surface disinfectant and the prohibition on the movement of fruit from a quarantined area into commercial citrus-producing States.

We established those conditions based on the conclusions of a pest risk assessment (PRA) and risk management analysis (RMA) prepared for the 2007 rulemaking. The PRA concluded that asymptomatic, commercially produced citrus fruit, treated with a disinfectant and subject to other mitigations, is not epidemiologically significant as a

¹ To view the proposed rule and the comments we received, go to (<http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2009-0023>).

² To view the November 2007 final rule, go to (<http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2007-0022>).

pathway for the introduction and spread of citrus canker.

The RMA examined the risks associated with both symptomatic and asymptomatic fruit and concluded that the introduction and spread of Xcc into other States through the movement of commercially packed fresh citrus fruit from quarantined areas is unlikely. In addition, the RMA concluded that a phytosanitary inspection would ensure, with high confidence, that few shipped fruit would have symptoms of citrus canker disease. However, the RMA also concluded that the evidence available at that time was not sufficient to support a determination that fresh citrus fruit produced in an Xcc-infested grove cannot serve as a pathway for the introduction of Xcc into new areas, thus necessitating the prohibition on movement of fruit into commercial citrus-producing States.

In our responses to public comments in the Background section of the November 2007 final rule, we stated: "If, in the future, evidence is developed to support a determination that commercially packed citrus fruit (both symptomatic and asymptomatic) is not an epidemiologically significant³ pathway for the introduction and spread of citrus canker, we would undertake rulemaking to amend our regulations accordingly."

Since the publication of the November 2007 final rule, two publications have provided additional evidence regarding the potential of fruit to serve as a pathway for the introduction and spread of citrus canker. This new evidence addresses key uncertainties and caused us to revisit our previous findings. The first article, by Gottwald *et al.* (2009), documents research on the survival of Xcc on commercially produced and packed citrus fruit and the likelihood that such fruit could serve as a mechanism to spread the disease. The second article, by Shiotani *et al.* (2009), documents research on the survival of Xcc on commercially produced mandarin fruits and the likelihood of spread of Xcc to trees from harvested mandarins.

Accordingly, we prepared updates to the PRA and RMA that had accompanied the November 2007 final

³ The term "epidemiologically significant" refers to the minimum conditions required for introduction of a disease into an unaffected area. Our judgment of whether fruit is an epidemiologically significant pathway for disease transmission is based on the likelihood that the fruit itself will be infected with the disease, that the infection will occur in a way or at a level sufficient for transmission of the disease, and that such an infected fruit will encounter the biological conditions required for transmission of the disease.

rule. The updated PRA, titled "An Updated Evaluation of Citrus Fruit (*Citrus* spp.) as a Pathway for the Introduction of Citrus Canker Disease (*Xanthomonas citri* subsp. *citri*)" (March 2009), examines the information presented in Gottwald *et al.* (2009) and Shiotani *et al.* (2009) in the context of the earlier PRA. Based on the evidence presented in both the November 2007 PRA and the two new publications, the updated PRA concludes that asymptomatic fruit (treated or untreated) is not epidemiologically significant as a pathway for introducing citrus canker. It further concludes that symptomatic fruit subjected to a packinghouse process that includes washing with disinfectants is also not epidemiologically significant as a pathway for introducing citrus canker.

These conclusions led us to prepare a supplemental RMA, titled "Movement of Commercially Packed Citrus Fruit from Citrus Canker Disease Quarantine Area; Supplemental Risk Management Analysis" (May 2009). The supplemental RMA takes into account the conclusions of the updated PRA as well as the evidence and discussion presented in the November 2007 RMA. Like the November 2007 RMA, the supplemental RMA was submitted for peer review, in accordance with the Office of Management and Budget's bulletin on peer review. All the materials associated with the peer review on the supplemental RMA, including the peer reviewers' comments and our responses, are available at (http://www.aphis.usda.gov/peer_review/peer_review_agenda.shtml). The peer reviewers' comments were considered in developing the supplemental RMA.

The supplemental RMA concludes that multiple lines of evidence, including, but not limited to, evidence from the two recent studies and the November 2007 RMA, indicate that commercially packed and disinfected fresh citrus fruit is not an epidemiologically significant pathway for the introduction and spread of Xcc, *i.e.*:

- Disease management practices in the grove reduce, but do not eliminate, Xcc populations.
- Commercially produced fruit harvested in areas where Xcc exists may be visibly infected or the fruit may carry the pathogen either on its surface or in wounds.
- Citrus canker disease development between harvest and packinghouse, via wounding for example, is not likely.
- Procedures for cleaning and disinfecting fruit are routinely applied by packinghouses.

- The individual efficacy of these procedures for removing or destroying Xcc may not be known in detail, but the effect of packinghouse treatments reduces the prevalence of viable Xcc and therefore the level of inoculum associated with commercially packed fresh citrus fruit.

- Packinghouse processing that includes a disinfectant treatment further reduces amounts of Xcc inoculum on infected or contaminated fruit.

- The viability of bacteria on fruit and in lesions and wounds diminishes after the fruit is harvested.

- The viability of Xcc bacteria that survive the packing process will further diminish during shipping.

- Epiphytic populations of Xcc may aid in pathogen dispersal, but substantial evidence indicates that bacterial populations do not infect intact mature fruit.

- Evidence indicates that wounds on harvested fruit containing Xcc inoculum do not lead to citrus canker lesion development, and Xcc populations generally decline rapidly, although wounds might occasionally retain Xcc populations that decline more slowly.

- The cool temperatures at which citrus fruit are stored and shipped and the duration of storage reduce the ability of Xcc to reproduce and cause infection.

- As a condition for successful establishment, Xcc, in amounts sufficient to cause infection, must encounter not only an environment with a conducive temperature, relative humidity, moisture, and wind events for infection, but also must encounter host plant tissue that is either at a susceptible growth stage or is wounded and then must successfully enter this tissue.

- Despite substantial international trade between Xcc-infected and noninfected countries, there is no authenticated record of movement of diseased fruit or seeds resulting in the introduction of Xcc to new areas.

In light of this evidence, the supplemental RMA considered five risk management options for the interstate movement of commercially packed citrus fruit from areas quarantined for citrus canker:

- *Option 1:* Allow distribution of all types and varieties of commercially packed citrus fruit to all U.S. States, without packinghouse treatment with a disinfectant.

- *Option 2:* Allow distribution of all types and varieties of commercially packed citrus fruit to all U.S. States, subject to packinghouse treatment with an Animal and Plant Health Inspection Service (APHIS)-approved disinfectant,

but without the current inspection requirement.

● *Option 3:* Allow distribution of all types and varieties of commercially packed citrus fruit to all U.S. States except commercial citrus-producing States, subject to packinghouse treatment of citrus fruit with an APHIS-approved disinfectant treatment; and, allow distribution of all types and varieties of commercially packed citrus fruit to all U.S. States, including commercial citrus-producing States, subject to packinghouse treatment with an APHIS-approved disinfectant treatment and APHIS inspection for symptoms of citrus canker.

● *Option 4:* Allow distribution of all types and varieties of commercially packed citrus fruit to all U.S. States other than commercial citrus-producing States, subject to packinghouse treatment with an APHIS-approved disinfectant.

● *Option 5:* Leave the current regulations for the interstate movement of citrus fruit from areas quarantined for citrus canker unchanged.

After considering the evidence presented in the updated PRA and the supplemental RMA and the conclusions of those documents, we determined that currently available scientific evidence provides additional certainty that commercially packed and disinfected fresh citrus fruit is not an epidemiologically significant pathway for the spread of Xcc. Therefore, no mitigations beyond treatment with an APHIS-approved disinfectant are necessary. Accordingly, we proposed to implement Option 2.

Several commenters acknowledged that the risk associated with the interstate movement of regulated fruit from a quarantined area is low but stated that, if there is any risk associated with allowing fruit to move from areas quarantined for citrus canker into commercial citrus-producing States, such movement should be prohibited. These commenters stated that citrus canker has been a destructive and costly disease in Florida, one which spurred an eradication attempt that was ultimately unsuccessful, and that other commercial citrus-producing States do not want to be at risk for the introduction and establishment of the disease. One commenter recommended that we err on the side of caution in making changes to the regulations and stated that further research should be done before fruit from quarantined areas is allowed into commercial citrus-producing States.

Two of these commenters proposed additional risk mitigation measures to address the risk they perceived to be

associated with fruit moved interstate from an area quarantined for citrus canker. Both stated that such fruit should not be allowed to move into the eight-county Citrus Zone in south Texas. These commenters cited the suitability of Texas' climate to citrus canker establishment (as demonstrated by previous outbreaks of citrus canker in Texas), the susceptibility of grapefruit (a common citrus crop in Texas) to citrus canker, and citrus canker's effect on young citrus trees. One of these commenters additionally requested that fruit destined for Texas originate only from groves that have been certified as being free of citrus canker for more than a year, based on a survey.

Another commenter, responding to some of these commenters, stated that no agricultural trade between States and countries anywhere in the world could be conducted if minimal risk is unacceptable and that the proposed rule would mitigate the risks to the point that risks are negligible.

Our goal in restricting the interstate movement of plants, plant products, and other articles is not to achieve zero risk, which, as the last commenter noted, cannot be achieved in agricultural trade. Rather, we seek to impose restrictions on the interstate movement of such articles that are commensurate with the risk they pose and that mitigate the risk associated with their interstate movement. Based on all the available scientific evidence, the updated PRA and supplemental RMA concluded that commercially packed and disinfected fresh citrus fruit is not an epidemiologically significant pathway for the introduction and spread of Xcc. We received several comments on the two new publications that led us to prepare the updated PRA and supplemental RMA, as well as comments on the updated PRA and supplemental RMA themselves. These comments are discussed in further detail later in this document. However, they did not change our conclusion that commercially packed and disinfected fresh citrus fruit is not an epidemiologically significant pathway for the spread of Xcc. Accordingly, this final rule implements Option 2 as proposed.

We are not retaining the current prohibition on the distribution of fruit from a quarantined area to commercial citrus-producing States, and we are not adding the additional mitigations requested by two of the commenters. Based on our determination that fruit is not an epidemiologically significant pathway, we have determined that those additional mitigations are unnecessary to prevent the spread of citrus canker

via the interstate movement of fruit from quarantined areas. As noted, it is impossible to eliminate all risk associated with the interstate movement of fruit from quarantined areas; given the conclusions of the updated PRA and the supplemental RMA, following the recommendation that we prohibit the movement of fruit into commercial citrus-producing States unless all risk is eliminated would impose an unnecessary restriction on the movement of fruit.

Under section 412(a) of the Plant Protection Act (7 U.S.C. § 7712), the Secretary of Agriculture may prohibit or restrict the interstate movement of any plant or plant product if the Secretary determines that the prohibition or restriction is necessary to prevent the dissemination within the United States of a plant pest or noxious weed. Based on our supplemental RMA, APHIS has concluded that commercially packed citrus fruit treated with an APHIS-approved disinfectant is not an epidemiologically significant pathway for the dissemination of citrus canker within the United States. Accordingly, APHIS has determined that it is not necessary to prohibit the interstate movement of regulated fruit that is commercially packed and treated with an APHIS-approved disinfectant from an area that is quarantined for citrus canker in order to prevent the dissemination within the United States of a plant pest. This determination is based on the findings of the updated PRA and the supplemental RMA referred to earlier in this document and our judgment that the application of the measures we proposed will prevent the dissemination of plant pests within the United States.

One commenter who was opposed to allowing the interstate movement of citrus fruit from a quarantined area to commercial citrus-producing States stated that California, a commercial citrus-producing State, is the home of three of the most important resources of citrus germplasm in the United States: The National Clonal Germplasm Repository for Citrus and Dates (NCGRCD), a U.S. Department of Agriculture-Agricultural Research Service (ARS) facility supplying budwood worldwide; the Citrus Clonal Protection Program, University of California-Riverside (UCR), the first citrus germplasm program in the world supplying budwood to California, Arizona, and Texas; and the UCR Citrus Variety Collection, perhaps the most diverse citrus collection in the world dating back to 1907. The commenter stated that certified disease-free budwood and a broad genetic basis for

variety development and improvement are the foundation of every successful, profitable, and sustainable citrus industry in the world and that those three germplasm resources are the only ones in the United States (if not the world) that have not been exposed to citrus canker or other devastating citrus diseases such as citrus greening. The commenter stated that taking a "calculated" risk to expose these invaluable resources to one of the worst citrus diseases in the world, citrus canker, based on limited field and packinghouse practices that will not be inspected for compliance is unacceptable. This commenter also stated that the Florida citrus industry funded a project to "rescue" Florida citrus germplasm by moving it to citrus canker- and citrus greening-free California in the NCGRCD facilities.

As we have determined that commercially packed and disinfected fresh citrus fruit is not an epidemiologically significant pathway for the introduction and spread of citrus canker, we do not expect that these facilities will be exposed to citrus canker as a result of the implementation of this final rule.

However, it should be noted that germplasm facilities are devoted to the preservation of the germplasm within the facilities and thus are protected against potential sources of pest and disease introduction. Indeed, potentially infected germplasm from foreign countries is imported into these same facilities for screening purposes, which is a much more likely pathway for the introduction of diseases such as citrus canker than the interstate movement of regulated fruit from a quarantined area. Allowing citrus fruit to be moved interstate from quarantined areas into California will not decrease the efficacy of the biosecurity in place at these facilities.

It should also be noted that, under this final rule, packinghouses will be inspected to ensure that they are complying with the requirements to treat regulated fruit with an APHIS-approved disinfectant and to ensure that the fruit is free of leaves, twigs, and other plant parts, except for stems that are less than 1 inch long and attached to the fruit. With regard to the other commercial fruit production practices described in the November 2007 RMA, we assume that commercial growers and packinghouses will continue to employ procedures that reduce the incidence of citrus canker in their fruit, as citrus canker lesions reduce the market value of infected fruit.

New Evidence We Considered in the Updated PRA and Supplemental RMA

Several commenters generally addressed the Gottwald *et al.* (2009) and Shiotani *et al.* (2009) publications. We address these comments below.

One commenter stated that the premise of both publications was to prove that citrus canker cannot be transmitted by infected or contaminated citrus fruit. The commenter stated that, scientifically, a negative premise cannot be proven, and the commenter cited this as one major flaw of these studies. Another commenter stated that Shiotani *et al.* (2009) did not demonstrate that Xcc cannot be transmitted from fruit to susceptible tissue, as it did not adequately resolve the ability of Xcc to spread from asymptomatic fruit.

One commenter, responding to the first commenter, stated that the two publications never set out to prove that something cannot happen because, philosophically and scientifically, this is impossible. However, the commenter stated, both publications soundly proclaim that risks can very effectively, very simply, and very reliably be reduced below any reasonable and measurable risk of transmitting citrus canker disease.

As the last commenter states, neither of the publications concluded that citrus canker cannot be spread by fruit. Gottwald *et al.* (2009) concluded that "harvested and packinghouse-disinfested citrus fruit are extremely unlikely to be a pathway for Xcc to reach and infect susceptible citrus and become established in canker-free areas." Shiotani *et al.* (2009) concluded that "there is a low risk [of] transmission" of Xcc from fruit. These conclusions are consistent with the conclusions of the updated PRA and supplemental RMA, as described earlier.

Two commenters stated that the research in the Gottwald *et al.* (2009) and Shiotani *et al.* (2009) publications should be tested and retested by others who were not involved in the original research before changing the conditions under which fruit is allowed to move from an area quarantined for citrus canker. Three commenters stated that a national task force consisting of scientists from citrus-producing areas other than Florida (and besides ARS personnel) should be assembled to address any change in current quarantine regulations that might result in the introduction of known destructive pathogens from known infected areas to noninfected areas (*i.e.*, California, Arizona, Texas, etc.).

The Gottwald *et al.* (2009) and Shiotani *et al.* (2009) publications were

produced independently, published in a peer-reviewed journal, and came to similar conclusions regarding the epidemiological significance of fruit as a pathway for the spread of citrus canker. Among other topics they address, these publications provide valuable evidence regarding the potential for Xcc to spread from infected fruit to host plants in the field; this evidence is what prompted us to prepare the updated PRA and supplemental RMA.

However, the updated PRA and supplemental RMA considered all the available evidence regarding the potential of fruit to serve as an epidemiologically significant pathway for the introduction and spread of citrus canker, not just the evidence in those publications. The weight of all the available evidence is what led us to the conclusion that commercially packed and disinfected fresh citrus fruit is not an epidemiologically significant pathway for the introduction and spread of Xcc. We have determined that the evidence provides adequate certainty regarding this conclusion to remove some restrictions on the interstate movement of commercially packed and disinfected fresh citrus fruit from an area quarantined for citrus canker.

The November 2007 PRA and RMA and the supplemental RMA prepared for this rulemaking were all submitted for peer review in accordance with the Office of Management and Budget's bulletin on peer review. The peer reviewers for the November 2007 PRA and RMA and the supplemental RMA were experts in plant pathology, phytobacteriology, and risk assessment. The comments we received from these peer reviewers indicated that our analysis of the available evidence regarding the risk associated with the movement of fruit from an area quarantined for citrus canker was sound.

It should also be noted that the authors of the Shiotani *et al.* (2009) publication were not affiliated with the State of Florida in any way, and the experiments in the Gottwald *et al.* (2009) publication were conducted by an international consortium of scientists working cooperatively and reaching the same conclusion after conducting similar experiments in two different countries, with participants from Argentina as well as Florida.

Gottwald et al. (2009)

We received several comments specifically addressing Gottwald *et al.* (2009).

Some of the experiments included in Gottwald *et al.* (2009) examined the

effectiveness of treatment with a disinfectant at reducing Xcc populations on citrus fruit. One commenter stated that the disinfection procedures significantly reduced pathogen survival but did not completely eliminate it. The commenter stated that, considering the large amount of fruit being shipped, even a low survival rate of the pathogen poses a high risk for the introduction of Xcc to a disease-free area.

This commenter also stated that the limitation of treatments in disinfecting fruit with lesions or fruit wounds contaminated with inoculum of the pathogen is well known. Oxidizing agents cannot effectively remove or reduce inoculum to acceptable levels in wounded tissue because of the natural reducing agents that occur in fruit tissue. Furthermore, these treatments would have little or no effect on established fruit lesions that act as reservoirs of inoculum. Thus, the commenter stated, without any inspections, even a few lesions on fruit would pose a high risk because the pathogen could not be eliminated using existing disinfection practices.

Another commenter stated that one cannot in a practical sense sterilize the surface of fruit; it would do more harm than good, and there is no biological reason to do so. The commenter stated that there is an inoculum threshold necessary to naturally establish citrus canker under even the most conducive conditions (10^5 colony-forming units (cfu)/milliliter (ml) for intact tissue infection, 10^3 cfu/ml for wounded) and that fruit disinfection easily achieves the low levels of inoculum necessary to avoid the risk of disease transmission. The commenter stated that the concern that inoculum in wounds on fruit could not be completely eliminated overlooks the fact that the bacteria do not even cause an infection at the wound site, let alone become liberated to possibly induce a lesion elsewhere.

The November 2007 RMA and the supplemental RMA both acknowledge the fact that disinfection treatments are not completely effective against Xcc bacteria in lesions. However, as the November 2007 RMA stated, there is abundant evidence that shows that packinghouse disinfection treatments destroy surface bacteria and reduce the viability of all bacteria on fruit. We did not rely solely on the Gottwald *et al.* (2009) publication in making our determination that treatment with an APHIS-approved disinfectant is an effective mitigation against the risk of spread of citrus canker; rather, we considered all the available evidence regarding the effectiveness of disinfectant treatments.

In addition, other evidence indicates that bacteria that remain in lesions after disinfection are not epidemiologically significant. For example, Gottwald *et al.* (2009) provided additional evidence supporting the conclusion that the viability of bacteria on fruit and in lesions and wounds diminishes after the fruit is harvested and that the viability of Xcc bacteria which survive the packing process will further diminish during shipping.

We disagree with the first commenter that the effectiveness of disinfectant treatment on bacteria in wounds is a concern. The second commenter is correct to note that Xcc bacteria in wounds do not cause infections at the wound site. As discussed in the supplemental RMA, evidence indicates that wounds on harvested fruit containing Xcc inoculum do not lead to citrus canker lesion development, and Xcc populations generally decline, although wounds might occasionally retain Xcc populations that decline more slowly.

Finally, with respect to the first commenter's concern about elimination of bacteria, we acknowledge that the surface disinfectant treatments approved by APHIS reduce numbers of Xcc cells to low or undetectable levels, but do not necessarily provide complete eradication. As the second commenter notes, complete eradication would be impractical. In any case, it is not necessary to completely eradicate Xcc in order to ensure that disinfected fruit is not an epidemiologically significant pathway. While the updated PRA and supplemental RMA conclude specifically that commercially packed and disinfected fresh citrus fruit is not an epidemiologically significant pathway for the introduction and spread of Xcc, it is not just the disinfection process that makes fruit not an epidemiologically significant pathway for Xcc, but also the biology of Xcc and the conditions that must be fulfilled in order for Xcc transmission from infected fruit to a host plant to occur, among other factors.

Some commenters addressed experiments in the Gottwald *et al.* (2009) publication that were designed to investigate the likelihood that citrus fruit disposed of by consumers may serve as a source of inoculum for nearby host material. Gottwald *et al.* (2009) studied the transmission of Xcc from unprocessed, infected 'Ruby Red' grapefruit and 'Lisbon' lemon and packinghouse-processed 'Ruby Red' grapefruit in cull piles to 'Duncan' grapefruit seedlings during natural weather events. During the course of the experiments, citrus canker lesions did

not develop on the grapefruit seedlings (488 seedlings total) surrounding the diseased fruit, in spite of extensive leafminer damage present on some of the seedlings. Xcc bacteria were not detected in assays of the foliage.

Gottwald *et al.* (2009) repeated the cull pile experiment to see if transmission of Xcc from infected, unprocessed 'Ruby Red' grapefruit fruit is possible under simulated extreme wind and rain conditions. Infected fruit were either placed in a cull pile or suspended by vertical strings. One seedling 0 meters (m) downwind from the cull pile became infected when subjected to the highest wind speed (25 m per second (m/s)) and simulated rain, developing 1 lesion on a single leaf injured by the action of the high-speed fan. The other 191 plants in the study did not develop Xcc lesions. No Xcc lesions developed on the 192 plants placed at the same distance and subjected to the same wind speed (0, 10, and 25 m/s with water) from Xcc-infected grapefruit suspended from string. Xcc was recovered from 1 collection screen set up 2 m from suspended fruit, but no Xcc was recovered from the other 144 collection screens set up at various distances (0 to 10 m) from cull piles or suspended fruit. Gottwald *et al.* (2009) stated that this cull pile experiment was "a highly contrived situation designed to provide every possible opportunity for dispersal of Xcc and would be unlikely to occur in most areas, except those locations where hurricanes or tropical storms are common occurrences."

One commenter noted that one plant surrounding infected fruit in cull piles did develop the disease in one of the simulated wind and rain experiments, indicating that this pathway of transmission is possible. The commenter stated that one might think that this level of transmission from an infected fruit to a healthy plant is very low, but this can be interpreted as very high under the set of conditions established for the experiments. The commenter stated that conducting these studies in regions where other environmental conditions exist and with a different group of scientists may lead to a different conclusion.

A second commenter stated that both Gottwald *et al.* (2009) and Shiotani *et al.* (2009) demonstrate that transmission of the bacterium is a difficult process to replicate and expressed a view that the natural spread of the bacterium from infected fruit to host plants remains poorly understood. The commenter stated that the cull pile transmission experiments conducted by Gottwald *et al.* (2009) do not provide conclusive

evidence that the risk of fruit-to-tree transmission is insignificant. The commenter stated that these trials were conducted with little replication and did not adequately represent weather events that are conducive to the transmission of the bacterium, that the authors did not demonstrate that Xcc could initiate infections under the experimental conditions in positive controls, and that the employed diagnostic methods were not tested in positive controls.

This commenter also noted that transmission of Xcc from infected fruit to host plants did occur, despite each wind speed treatment being applied for only 5 minutes. While APHIS concluded that the experimental conditions that produced this result were "highly contrived," the commenter stated, due to the small-scale nature of this trial, small sample sizes, short exposure times, and lack of adequate controls, the risk of transmission under natural conditions remains feasible and significant. The commenter concluded that the experiments by Gottwald *et al.* (2009) demonstrated the ability of Xcc to be spread from symptomatic citrus fruit.

A third commenter stated that the transmission of Xcc from infected fruit to host plants in the simulated extreme wind and rain conditions was probably because of mechanical contact and injury, not from anything most people would consider as a natural transmission event. This commenter also noted that the cull pile in that experiment was composed of freshly picked and heavily infected fruit, not fruit that had been graded and disinfected according to packinghouse protocol. The commenter stated that the value of this experiment is that it demonstrates the "tipping point" for canker infection from fruit. The commenter stated that if the other commenters envision a pile of freshly picked canker-infected grapefruit suddenly arriving in a grapefruit orchard in Australia, Arizona, or California immediately adjacent to susceptible plants and experiencing 25 m/s winds accompanied by rain, the scenario is excessively imaginary. The "tipping point," in this commenter's view, identifies the dangerous conditions for shipping fresh fruit from a canker endemic area so they can be completely avoided.

We agree with the first two commenters that it would have been optimal to have additional replications of the experiment in which Xcc was transmitted from infected fruit to host plants, to better determine the rate at which transmission occurs in these

conditions. However, as noted, the conditions in the experiment in which Xcc was successfully transmitted from infected fruit to host plants were extreme conditions, designed (as the third commenter states) to establish whether transmission of Xcc from infected fruit to host plants is possible, not whether it is likely. (As the third commenter notes, Gottwald *et al.* (2009) concluded that the lesion that resulted from the simulated wind and rain cull pile experiment "was the result of a leaf wound.")

In the context of the other experiments Gottwald *et al.* (2009) performed to assess the likelihood of fruit-to-plant transmission, and in the context of the conditions of the experiment, including not only the simulated extreme wind and rain conditions but also the fact that the fruit were unprocessed and untreated and the placement of those fruit directly adjacent to host plants, we have determined that this one successful transmission is consistent with a determination that commercially packed and disinfected fresh citrus fruit is not an epidemiologically significant pathway for the introduction and spread of Xcc, given all the available evidence about the potential for fruit to serve as a pathway.

Although the first commenter is correct that conducting the experiments in other environmental conditions and with another group of scientists might lead to a different conclusion, based on the available science regarding the transmission of citrus canker, the environmental conditions under which these experiments were conducted are extremely suitable to the potential transmission of citrus canker. Fruit that were specifically selected for their high level of infection and that were subjected to none of the packinghouse processes (including disinfection) that are known to reduce the viability of Xcc infection were used in attempts to infect highly susceptible grapefruit plants at the most susceptible stage of the plants' development. The one trap plant that was infected was placed immediately adjacent to the infected fruit and subjected to simulated extreme wind and rain conditions that are unlikely to occur in most areas. We have determined that it is unlikely that studies in other regions and under other environmental conditions would produce a greater level of transmission of the disease from infected fruit to host plants.

We have determined that the Gottwald *et al.* (2009) experiments adequately represented weather events that are conducive to the transmission

of Xcc and represented a range of weather conditions as well. The trials were conducted both in field conditions that were not conducive to the transmission of Xcc, in Argentina, and that were conducive, in Florida.

It would be difficult to develop a positive control for the cull pile experiments, as a positive control would require the successful transmission of Xcc, which Gottwald *et al.* (2009) were only able to accomplish under conditions described in the publication as "highly contrived." (It should be noted that this was not APHIS' description.) Nevertheless, it should be noted that the authors who performed the cull pile experiments have performed similar experiments using yard blowers, as documented in Bock *et al.* (2005) and Parker *et al.* (2005). These publications demonstrated that using a forced air source for wind and hose water for rain will elicit and spread Xcc from infected plants. In one experiment in Bock *et al.* (2005), the blower was run for 5 minutes, the same duration as in the 25-m/s artificial wind and rain cull pile experiment, and bacteria were recovered from the water to which the infected plants were exposed. Different experiments in both papers using different durations produced the same results. We would presume that using similar techniques to elicit and spread Xcc from infected fruit would be effective, if fruit was an epidemiologically significant pathway.

The commenter correctly notes that the Gottwald *et al.* (2009) publication did not describe any positive controls for the immunostrips used in the cull pile experiments to determine whether Xcc was present. However, a personal communication with one of the authors of that publication indicates that the experimenters did use positive controls to confirm that the immunostrips were working properly and thus would have indicated that Xcc was present if it had been present.

We disagree with the second commenter that the exposure times in the cull pile experiments in Gottwald *et al.* (2009) were "short." The 5-minute exposure time in the 25-m/s artificial wind and rain experiment was sufficient to infect 1 test plant. The commenter also ignores the field cull pile experiments, which each took place for several weeks, at different times of year.

Finally, it is important to note that our determination that commercially packed and disinfected fresh citrus fruit is not an epidemiologically significant pathway for the introduction and spread of Xcc does not rest solely upon the Gottwald *et al.* (2009) cull pile experiments, although they do provide

valuable evidence supporting that determination. Rather, that determination takes into account all the evidence considered in the November 2007 RMA, the updated PRA, and the supplemental RMA, including evidence about the biology of the disease, the effectiveness of disinfectant treatment, the conditions that must be fulfilled for disease transmission to occur, and the fact that the movement of commercial citrus fruit has not been associated with an outbreak of the disease anywhere in the world.

Shiotani et al. (2009)

We also received several comments specifically addressing Shiotani *et al.* (2009).

One commenter stated that, in Shiotani *et al.* (2009), proper positive controls proving that the polymerase chain reaction (PCR) detection technique is working were not included in one set of experiments. (We believe the commenter is referring to the examination of fruit collected from a diseased commercial orchard to investigate the survival of Xcc.) The commenter stated that the lack of controls casts doubts on the results of this research.

The commenter correctly notes that there is no explicit discussion of controls in the "Materials and Methods" section of the paper. This does not mean that the proper controls were not used, but we cannot verify that they were. That said, the fact that isolations and bioassays made from the same material also yielded negative results supports the PCR results.

One commenter stated that the Shiotani *et al.* (2009) experiments used a laboratory strain of Xcc that has not been shown to be pathogenic but, the publication stated, "is believed to be as robust as the wild-type." The commenter stated that this demonstrates critical flaws in the experimental design and that the conclusions of Shiotani *et al.* (2009) can thus not be accepted without reasonable doubts.

The commenter quotes from the "Discussion" section of the Shiotani *et al.* (2009) publication. In the "Materials and Methods" section, the authors discuss the laboratory strain in more detail: "A marked strain of *X. citri* pv. *citri* (KC21Rif100) that is resistant to rifampicin was used as inoculum. This strain is a stable, spontaneously derived mutant from strain KC21 (Shiotani *et al.*, 2008), which has been shown to be as pathogenic as other strains of *X. citri* pv. *citri* in infection studies." We believe this information addresses the commenter's concern.

The Shiotani *et al.* (2009) publication included experiments designed to assess the potential for spread of Xcc from mature Satsuma mandarin fruit inoculated with the marked strain of Xcc mentioned above and suspended in polypropylene net bags in navel orange trees. One commenter noted that, in one of the four experiments conducted, citrus canker was transmitted from culled mandarin fruit to leaves of navel orange trees in an orchard.

Another commenter, responding to the first commenter, noted that the infections in that experiment were not caused by the marked strain of Xcc but by the wild type. Citrus canker is endemic in the area where this study was done, so a tagged strain was used. That way, the commenter stated, the researchers have an idea where the inoculum is coming from. The commenter stated that the fact that wild-type canker bacteria occasionally are caught in traps or cause infection on plants in the experiment does not undermine the conclusion in any way; in fact, it demonstrates that conditions conducive to the transmission of canker existed, and the marked strain on and in fruit did not demonstrate any risks of disease transmission.

We agree with the second commenter.

One commenter stated that the Shiotani *et al.* (2009) publication does not provide a high degree of confidence that transmission of Xcc from contaminated fruit to host plants is not epidemiologically significant. Although no transmission of Xcc was observed, the commenter suggested that it is possible that this was due to unexplained variables. Rainfall data were provided but no information was provided on the growth stage of trap plants, insect presence in the orchard, potential wounds and insect damage, spray history within the orchard, or other significant wind and weather events. Because the experiments were conducted in a commercial orchard, the commenter stated, it would be expected that pest and disease management would have been practiced at some point prior to the study.

As noted earlier, the Shiotani *et al.* (2009) experiments used a marked strain of Xcc because Xcc is endemic in the area where the experiments took place. The wild-type strain of Xcc occurred in the orchard where the experiments took place, throughout the experiments. This indicates that at least some plants in the orchard were at a susceptible growth stage, and in general the transmission of Xcc between trees in the orchard indicates that whatever unexplained variables may have been

present did not impede the normal transmission of Xcc.

In Shiotani *et al.* (2009), the authors state, for the initial assay of fruit from diseased orchards, "No chemicals had been sprayed to control the disease," addressing the commenter's concern about the previous employment of disease control methods. Disease control is not addressed directly for the other experiments, including the experiments regarding the potential spread of Xcc from Satsuma mandarin fruits. However, other statements in the publication imply that no disease control techniques were employed in the orchard:

In September 2006, the Satsuma mandarin orchard in Saga was damaged by typhoon No. 0613. The typhoon brought rain with strong southerly winds with maximum speeds of 50 m/s to the orchard, which is located on a south-facing hillside. The severe meteorological conditions of this typhoon strongly facilitated spread of citrus canker, leading to the highest incidence of the disease in the orchard in the last decade. ... It is most likely that small populations of the wild strain of *X. citri* pv. *citri* survived in the orchard. Citrus canker infection caused by the wild strain indicated that conditions were also conducive for the establishment and spread of the introduced KC21Rif100 strain. The KC21Rif100 strain did not exude from lesions on Satsuma mandarin fruits after they were discarded in an orchard in October 2006, although conditions were conducive for the spread of *X. citri* pv. *citri*.

If disease control techniques had been employed in the orchard, we assume that the authors would not have described the conditions as conducive for the spread of Xcc.

These statements also indicate that information on significant wind and water events was provided, specifically with regard to typhoon No. 0613.

Shiotani *et al.* (2009) did not provide any information on insect presence or pest control in the orchard. The citrus leafminer is known to occur in Japan, but we do not know whether it occurs in the orchard. However, it is important to note that insects themselves are not known to be vectors for Xcc; the presence of the citrus leafminer or another insect in the orchard might increase the severity of canker in the orchard, but it would not enable transmission of Xcc from infected fruit to host plants.

The commenter stated it is likely that naturally infected tissues have a higher

ability to transmit the bacterium than artificially surface-inoculated fruit, which were used in Shiotani *et al.* (2009).

Shiotani *et al.* (2009) determined that the bacteria in the lesions that resulted from the artificial inoculation were viable. We know of no evidence that suggests that bacteria in natural lesions are more effective than surface-inoculated bacteria in spreading Xcc, and the commenter did not supply any.

The commenter stated that another limitation of the design of this experiment is that it did not include a control group to demonstrate tree-to-tree transmission under a similar set of conditions.

Tree-to-tree transmission was demonstrated through the incidence of the wild-type strain of Xcc, which the publication discussed. In this case, the wild-type strain acted as a control to show that transmission of Xcc within the orchard was possible and did occur.

The commenter also stated that the uncertainties cited by the commenter are acknowledged by the authors, who suggested that conditions may have been unfavorable for spread of the bacterium.

The statement in Shiotani *et al.* (2009) that conditions may have been unfavorable for disease spread referred to one replication of the experiment. The publication goes on to note that disease spread occurred at high levels in a subsequent replication:

In the experiments started in November 2005 and March 2006, no canker symptoms were observed on any branches beneath the discarded fruits. This may be because weather conditions were unfavourable for disease spread during this period. During the experiment started on May 2006, canker lesions were observed on leaves of navel oranges located beneath the discarded Satsuma mandarin fruits. ...The severity of the disease was greater in 2006 than in 2005. The incidence of citrus canker in the orchard was 36.2 percent and severity was 18.0. The high incidence may be attributed to typhoon No. 0613 that occurred on September 17, 2006.

In addition, it should be noted that our determination that commercially packed and disinfected fresh citrus fruit is not an epidemiologically significant pathway for the introduction and spread of Xcc does not rest solely on the experiments in Shiotani *et al.* (2009), although they do provide valuable evidence supporting that determination. Rather, that determination reflected our analysis of all the evidence considered

in the November 2007 RMA, the updated PRA, and the supplemental RMA, as discussed earlier.

Shiotani *et al.* (2009) also examined the survival of Xcc bacteria on the surface of artificially inoculated fruit that were retained for sampling. One commenter noted that viable Xcc was isolated from 3 canker lesions from 2 out of 6 Satsuma mandarin fruit (a cultivar resistant to citrus canker), 3 months after inoculation. Given these results, the commenter concluded that symptomatic citrus fruit (treated or untreated) remain a potential source of inoculum.

We agree with the commenter that some viable bacteria may remain in lesions of infected fruit. However, in those fruits, the strain KC21Rif100 was found in only 3 of 14 lesions and at a bacterial population lower than 3×10^3 cfu per lesion. This is consistent with one of the findings of the November 2007 RMA and the supplemental RMA, which is that the viability of bacteria on fruit and in lesions and wounds diminishes after the fruit is harvested. Diminishing bacterial populations are less likely to provide adequate inoculum to incite infection.

It should also be remembered that the fruit that were sampled and found to have viable bacteria had been stored in protected conditions. The fruit that were artificially inoculated and used in the experiment regarding the potential of spread of citrus canker did not serve as sources of citrus canker transmission, even when the lesions had just been formed and presumably contained high levels of inoculum. The rinds of the artificially inoculated fruits retrieved after 3 days in the orchard did not have any viable bacteria. Finally, as noted earlier in the discussion of Gottwald *et al.* (2009), other evidence indicates that bacteria that remain on the fruit in lesions and wounds after disinfection are not epidemiologically significant.

The commenter is correct to note that Satsuma mandarin is a resistant variety of citrus. As noted in the supplemental RMA, the Gottwald *et al.* (2009) and Shiotani *et al.* (2009) publications used citrus cultivars that represented the extremes of susceptibility from highly susceptible (grapefruit) to less susceptible varieties (lemon, mandarins). APHIS assumes cultivars not specifically studied would fall within this range of susceptibility and the results are therefore applicable to all citrus cultivars. In any case, the supplemental RMA and November 2007 RMA consider many different sources of evidence in making the determination that the viability of bacteria on fruit and in lesions and wounds diminishes after

the fruit is harvested, not just the Shiotani *et al.* (2009) publication.

One commenter noted that the authors of Shiotani *et al.* (2009) state: "It is possible that bacterial cells of KC21Rif100 strain could not grow and colonize the surface of the contaminated fruits due to lack of nutrients." The commenter stated that, considering that at least a small percentage of fruit is always decaying during shipment and marketing, this decayed fruit can contaminate other fruit with nutrients that will make survival of the bacteria more likely.

The commenter provided no evidence suggesting that this would occur, and we are aware of none. The available evidence suggests that rotting fruit would not provide nutrients that would make survival of Xcc bacteria more likely. For example, Fulton and Bowman (1929) demonstrated that canker does not survive on rotting fruit. In addition, decaying fruit would be decaying due to the presence of other organisms, and Xcc does not compete well with other organisms, as described in Fulton and Bowman (1929) and Leite (1990).

One commenter stated that, at the end of the Shiotani *et al.* (2009) publication, the authors indicate that navel oranges are more susceptible to canker than mandarins. The commenter stated that this indicates that their pathogen survival studies on mandarins will not reflect the true risk of transmission of the pathogen/disease. Two other commenters echoed this concern and stated that, because California's growing situation is quite different than those in the research areas, there are serious issues about the extrapolation of data from study of only a few varieties. Another commenter, approaching this issue differently, suggested that restrictions on the interstate movement of different varieties of citrus fruit could vary based on the variety's resistance to citrus canker.

The Shiotani *et al.* (2009) publication does not actually state that Satsuma mandarins are more resistant to Xcc than navel oranges, although this is widely acknowledged to be true. In any case, as noted earlier, the Gottwald *et al.* (2009) and Shiotani *et al.* (2009) publications used citrus cultivars that represented the extremes of susceptibility from highly susceptible (grapefruit) to less susceptible varieties (lemon, mandarins). APHIS assumes cultivars not specifically studied would fall within this range of susceptibility and the results are therefore applicable to all citrus cultivars. The commenters did not provide any specific reasons to question this assumption.

In general, although we recognize that there are limitations in extrapolating from results achieved with Satsuma mandarins, the Shiotani *et al.* (2009) provides valuable evidence supporting our determination that commercially packed and disinfected fresh citrus fruit is not an epidemiologically significant pathway for the introduction and spread of Xcc. We took this evidence into account along with the Gottwald *et al.* (2009) publication and the other evidence cited in the November 2007 RMA and the supplemental RMA in making this determination.

Other Issues in the Updated PRA and Supplemental RMA

One of the conclusions in the updated PRA is that standard packinghouse procedures and post-harvest treatments will remove and/or devitalize epiphytic populations of Xcc. This conclusion is echoed in the supplemental RMA.

One commenter stated that the conclusion in the updated PRA that Xcc has a low survival potential is in contrast to earlier research by Golmohammadi *et al.* (2007), who reported that Xcc was frequently detected on fruit with canker-like symptoms in commercial consignments of citrus from Uruguay and Argentina into Spain. These consignments were accompanied by phytosanitary certification stating that fruit had been treated with postharvest bactericides, including chlorine and sodium orthophenylphenate. The presence of Xcc on these samples was confirmed by molecular and pathogenicity testing. Pathogenicity assays on grapefruit leaves confirmed that Xcc cells remained viable and were able to produce symptoms despite the application of postharvest treatments and low temperature storage.

Both the updated PRA and the supplemental RMA addressed Golmohammadi *et al.* (2007). The updated PRA and supplemental RMA state that the results in Golmohammadi *et al.* (2007) indicate that disinfection protocols are not 100 percent effective. Some samples were only positive by PCR protocols. The authors concluded this was probably due to the disinfection treatments, which would reduce bacterial populations, and may induce the noncultivable state in the analyzed lesions. They further suggested that the bacterial cells in the lesions could be stressed after the fruit treatments (washing, disinfection, chemical treatments, transport, and storage at low temperatures for variable periods of time). Pathogenicity tests were successfully conducted only by artificial laboratory inoculations; the

epidemiological significance of these results was not evaluated.

Pathogenicity tests of bacteria in the laboratory do not indicate whether the bacteria would actually be able to infect host plants in a field setting, where conditions are likely to be less favorable than in a laboratory. The fact that Golmohammadi *et al.* (2007) concluded that bacterial cells in the lesions could be stressed after the fruit treatments suggests that the bacteria would not have been able to do so, particularly given the results of the experiments Gottwald *et al.* (2009) and Shiotani *et al.* (2009) conducted that addressed the transmission of Xcc from infected fruit to host plants in the field. Since Gottwald *et al.* (2009) and Shiotani *et al.* (2009) both used untreated fruit in their experiments, and Golmohammadi *et al.* (2007) concluded that packinghouse processing and disinfection treatment further reduce the viability of the bacteria, we have determined that the results of Golmohammadi *et al.* (2007) are consistent with the determination that commercially packed and disinfected fresh citrus fruit is not an epidemiologically significant pathway for the introduction and spread of Xcc.

One commenter, specifically noting the detections of Xcc on fruit with canker-like symptoms in commercial consignments of citrus from Uruguay and Argentina into Spain, stated that standard harvesting and packinghouse procedures may not effectively eliminate infected fruit from the export pathway.

Both the November 2007 RMA and the supplemental RMA acknowledge this. However, these procedures do reduce the prevalence of viable Xcc in commercial consignments of fruit, thus bolstering the conclusion that commercially packed and disinfected fresh citrus fruit is not an epidemiologically significant pathway for the introduction and spread of Xcc.

One commenter stated that the supplemental RMA claims that the “uncertainties” recognized in the November 2007 RMA are now answered, but the question of additional “uncertainties” is completely disregarded.

The supplemental RMA has an extensive discussion of remaining uncertainties in the discussion of options at the end of the document. The commenter did not identify any specific uncertainties that the supplemental RMA did not address.

One commenter stated that, in the supplemental RMA, there is not a single biological reference to fruit pests such as the peel miner and to the fact that

there is no scientific work/information for its impact on diseases such as citrus canker. The supplemental RMA simply disregards this classic epidemiological factor under the general assumption “Vectors do not have a role in disease epidemiology and if they do, it is not subject to regulation.” The commenter stated that this disregard of valid, researchable questions is highly disturbing.

The role of insects in citrus canker outbreaks was discussed in the November 2007 RMA. The supplemental RMA does not recreate or revise the entire body of evidence cited in the November 2007 RMA, but rather builds on that body of evidence and evaluates those areas of evidence addressed by the new research. Because none of the newer research cited in the supplemental RMA addressed the role of insects in citrus canker outbreaks, we did not update the discussion in the November 2007 RMA.

With regard to the issue of vectors, one commenter stated that canker is a local lesion disease that does not invade the vascular system and is not transmitted by sucking insects or mites, including citrus leafminer and peel miner. The commenter stated that citrus leafminer is not a vector for the canker bacterium.

The November 2007 RMA indicates that injuries caused by the Asian leafminer can produce wounds that serve as infection courts in leaves and, to a lesser extent, fruit, but the leafminer itself is not known to be a vector for the spread of citrus canker. In the November 2007 final rule, we discussed the peel miner, stating that injuries from the peel miner would be likely to increase the susceptibility of fruit to infection, and increase the severity of the infection if they became infected. In terms of overall spread of citrus canker, however, the peel miner would not likely be as epidemiologically significant as the Asian leafminer, since leaves of citrus trees and plants are more susceptible to citrus canker infection than the peels of citrus fruit.

We also note that there exists no evidence indicating that the peel miner is a vector for citrus canker, and we would presume that the peel miner is not a vector, for the reasons cited by the second commenter.

Comments on the November 2007 RMA

The November 2007 RMA contained a discussion of the potential for introduction and establishment of Xcc in various climatic conditions.

One commenter stated that the idea that California has unfavorable environmental conditions for pathogen

establishment is simply untrue. The commenter stated that summer monsoons commonly go through the Imperial Valley, and thunderstorms with high winds occasionally occur in the Central Valley (both important citrus-producing areas of California), while humidity can reach adequate levels for canker establishment in the coastal areas of Ventura County (lemon-producing areas).

The November 2007 RMA states: "Using hourly wind speed and precipitation, monthly average temperature, and annual and seasonal precipitation data to determine the expected incidence and severity of citrus canker if introduced into California, Borchert *et al.* (2007) concluded that favorable events in California citrus growing areas occurred '... predominantly during the winter season when precipitation is greatest, but temperatures are less conducive for infection activity and citrus growth. This would likely result in low incidence and severity of citrus canker in California if the disease were introduced...' ...The 'Mediterranean' climate (dry summers) typical of most of California and the arid climate of Arizona make [Xcc] establishment less likely in those States. However, in microclimates with highly susceptible cultivars such as along the California coast between San Diego and Ventura establishment is still possible, as demonstrated by the occurrence of citrus canker disease in Iran and the Arabian Peninsula on a highly susceptible variety of Mexican lime."

We acknowledge that, as the commenter stated, summer monsoons and thunderstorms occur in California, but that is not inconsistent with the discussion in the November 2007 RMA. The information presented by the commenter has not led us to change the conclusions in the November 2007 RMA regarding the suitability of California's climate for the establishment of citrus canker.

One commenter stated that we should have more solid information on the source of previous outbreaks before making the changes we proposed.

The November 2007 RMA also analyzed the information available on the source of previous outbreaks. It concluded, "In summary, there is an unfortunate lack of conclusive information regarding the origins of previous outbreaks. Most published accounts are speculative. However, whatever the lack of certainty may be regarding the theories of [Xcc] introduction pathways, they all agree that trees or propagative tree parts are most likely the original source of [Xcc]

introduction. Conclusive evidence that fresh fruit is a pathway for the introduction of [Xcc] has never been presented." The November 2007 RMA also noted, and the supplemental RMA repeated, that "no canker outbreaks have ever been associated with the entry of fruit into the United States or anywhere in the world, nor has the ability of fruit to serve as a pathway of [Xcc] dissemination ever been demonstrated in any scientific experiment, and it seems very unlikely that fruit would be an epidemiologically significant pathway."

The evidence that has been developed and presented in the two studies that prompted the preparation of the updated PRA and supplemental RMA is consistent with the historical record on the source of citrus canker outbreaks, which largely ties them to the movement of infected nursery stock rather than the movement of infected fruit.

Compliance Agreements and Leaves

In addition to the requirement for treatment with an APHIS-approved disinfectant, we proposed to retain the requirement that regulated fruit moved interstate from an area quarantined for citrus canker be free of leaves, twigs, and other plant parts, except for stems that are less than 1 inch long and attached to the fruit. We proposed to retain this requirement because other plant parts pose different risks than fruit does; canker lesions on leaves, for example, typically have much higher bacterial populations than canker lesions on fruit.

In the Background section of the proposed rule, we stated that, under the proposed rule, APHIS inspectors would no longer be on site at packinghouses to enforce the requirements for treatment and removal of leaves, twigs, and other plant parts. We would require in our compliance agreements with commercial packinghouses that these activities be conducted in accordance with the regulations, and inspections would be conducted to ensure that treatment is being performed properly and that no leaves, twigs, or other plant parts are being included in containers of fruit moved interstate.

Two commenters stated that eliminating mandatory inspection of fruit to be moved interstate for visible symptoms of citrus canker raises questions about how APHIS will assure adherence to compliance agreement requirements.

As stated, we will continue to inspect commercial packinghouses that pack fruit to be moved interstate to verify that they are adhering to the requirements in

the regulations, as agreed to in the compliance agreement. These inspections will be conducted regularly. Inspectors will check treatments to ensure that they are being performed in accordance with the regulations (for example, verifying the pH level and the concentration in a sodium hypochlorite treatment). Inspectors will also open and inspect a random sample of packed boxes of fruit to verify that the packed fruit is free of leaves, twigs, and other plant parts. We have experience successfully enforcing compliance agreements with similar requirements for many other domestic quarantine programs.

One commenter stated that inadvertent citrus leaves included in packed boxes of fruit may also carry the pathogen/disease from one location to another.

Another commenter stated that, in the very unlikely event that a lesioned leaf would be present in a fruit load, conclusions that fruit is not an epidemiologically significant pathway can confidently be extended to aging and drying leaves. The commenter stated that it is unlikely that this source of inoculum would represent any different risk than fruit for inoculum production and disease transmission.

Although the second commenter may be correct, we have not undertaken a thorough assessment of the risks associated with allowing the interstate movement of leaves of regulated species from a quarantined area. We would need to do so before allowing the interstate movement of leaves. Therefore, we proposed to retain the requirement discussed earlier.

The first commenter is correct that leaves could inadvertently be moved in boxes of packed fruit. However, the requirement that fruit be free of leaves serves to mitigate that risk, as packinghouse employees will need to check to make sure that leaves are not inadvertently packed so that the packinghouse will be able to pass inspections conducted under the compliance agreements and continue to pack fruit for interstate movement. In addition, leaves are commonly removed from boxes of packed citrus fruit as part of commercial production practices. Given these conditions, we have determined that it is not necessary to provide for any further restrictions on the interstate movement of fruit in order to prevent the inadvertent interstate movement of leaves.

Citrus Greening

One commenter stated that we should consider ongoing research on evaluating citrus fruit as a potential source for the

Asian citrus psyllid (ACP), the vector of citrus greening, to acquire citrus greening.

Restrictions on the movement of certain articles due to the presence of citrus greening have been put in place under separate Federal orders; the initial order was issued on September 16, 2005, and was last updated on September 21, 2009. The September 21, 2009, Federal Order does not restrict the interstate movement of fruit from an area quarantined for ACP, except to require that the fruit be cleaned using normal packinghouse procedures. These procedures are sufficient to remove ACP. Fruit itself has not been shown to be a potential pathway for the spread of citrus greening.

The commenter did not cite any specific research that is ongoing regarding ACP's ability to acquire citrus greening directly from fruit, and we are not aware of any. However, if we determine that additional restrictions need to be placed on the interstate movement of fruit from areas quarantined for ACP, we would include those restrictions in a new Federal Order or in separate citrus greening regulations, not in the citrus canker regulations.

Illegal Movement of Nursery Stock

Section 301.75-6 of the regulations prohibits, with limited exceptions, the interstate movement of citrus nursery stock from an area quarantined for citrus canker. Three commenters stated that the potential illegal movement of nursery stock was the most risky pathway for the introduction of citrus canker into commercial citrus-producing States other than Florida. One recommended that, given the limited resources available to plant health regulatory programs, resources should be concentrated on this pathway. This commenter requested additional resources to deal with the pathway.

One stated that adoption of the proposed rule would likely increase the illegal movement of Florida citrus nursery plants into Texas, simply because the general public may conclude it is safe to transport citrus nursery plants as well.

Two of the commenters stated that efforts should be undertaken to increase public awareness of the prohibition against moving nursery stock interstate from citrus canker quarantined areas. Both of these commenters also requested that enforcement efforts against this illegal movement continue; one requested increased resources for those efforts.

We agree with these commenters that the illegal movement of nursery stock is a high-risk pathway. We have several efforts underway to prevent the spread of citrus canker and citrus greening through the illegal movement of nursery stock. In fiscal year 2009, we conducted enforcement activities that included:

- Monitoring of retail markets and wholesale distributors in commercial citrus-producing States;
- Monitoring the Internet for the sale and distribution of citrus plants from quarantined areas;
- Monitoring retail and wholesale establishments in States other than commercial citrus-producing States for citrus plants and plant products from quarantined areas; and
- Conducting operations in concert with State officials at State checkpoints to ensure that shipments moving out of Florida do not contain plants or plant products whose movement is prohibited and that shipments entering commercial citrus-producing States do not contain such products.

We are also sampling nursery stock that is found moving illegally to determine whether it is infected with a citrus disease. In all these activities, we work with State and local agencies, and we notify them of whatever violations we discover.

We are also conducting extensive outreach efforts regarding the movement of nursery stock from quarantined areas. The Web site (<http://www.saveourcitrus.org>) provides a public clearinghouse of information on safeguarding U.S. citrus resources and preventing the illegal movement of citrus plants from quarantined areas. We will continue to employ resources on enforcement and outreach as necessary and as budget constraints allow.

We disagree with the commenter who stated that the proposed rule would likely increase introduction of illegal Florida citrus nursery plants into Texas. Although regulated fruit has been allowed under the regulations to move interstate to States other than commercial citrus-producing States, regulated nursery stock, except kumquat plants produced under conditions designed to prevent their infection with citrus canker, is not allowed to move interstate. Thus, the difference between the allowable movement of regulated fruit and regulated nursery stock already exists, and our enforcement and outreach efforts take it into account.

International Trade

Two commenters expressed concern regarding trade issues. Both expressed concern that the rule might result in trading partners imposing additional

restrictions on the export of citrus fruit from the United States. One stated that we should not finalize the proposed rule until we know that the European Union (EU) agrees with the science that serves as a basis for the rule, citing fears of trade interruptions.

Another stated that the objective of the rule was to demonstrate to our trading partners that there is no risk of spread of citrus canker via fruit, thus allowing Florida to export fresh fruit to countries that currently restrict or prohibit such importations. This commenter stated that jeopardizing citrus-producing areas in the United States so that Florida can trade with citrus-producing areas around the world is unacceptable.

Regulated fruit from Florida is currently exported to other countries, including the EU, in accordance with those countries' regulatory requirements. We proposed to relieve restrictions on the interstate movement of fruit from an area quarantined for citrus canker based on our determination that commercially packed and disinfected fresh citrus fruit is not an epidemiologically significant pathway for the introduction and spread of citrus canker, not as part of an attempt to reduce or remove restrictions on the exportation of Florida citrus fruit to other countries. Other countries are not obligated to change their requirements for the importation of plant products based on changes in our regulations on the interstate movement of plant products.

We are willing to have exchanges with foreign national plant protection organizations to discuss our findings, but because we have determined the restrictions that have been in place on the movement of fruit from a quarantined area are no longer justified by the scientific evidence, we are removing restrictions that are no longer warranted.

Kumquats

One commenter requested that we remove kumquats from the list of regulated articles in § 301.75-3(a), thus allowing kumquat fruits to be moved interstate from the quarantined area with leaves and stems, as they are commonly marketed. The commenter stated that there has not been any citrus canker found in Pasco County, FL, where all of the commenter's kumquats are grown, and that there has been no citrus canker found in commercial kumquat groves. The commenter also stated that a professor at the University of Florida's horticulture department has stated that "Nagami kumquats and citrus canker are incompatible...Far

from acting as a host, the Nagami kumquats suppress it by causing the inoculated tissue to die and the affected leaves to fall off.”

Although there are numerous references stating that kumquats are highly resistant to citrus canker (see Gottwald *et al.* (2002) and Francis *et al.* (2009)), we are aware of no references that state that citrus canker does not infect kumquats, or that kumquats are incompatible with citrus canker. For that reason, we list kumquat plants and plant parts (including fruit, leaves, and stems) as regulated articles in § 301.75-3(a). If evidence is developed that indicates that citrus canker does not infect kumquats, we will amend the list of regulated articles accordingly.

With respect to the commenter's specific concern, we note that if kumquats were removed from the list of articles regulated for citrus canker, kumquat leaves would still be prohibited from moving interstate from Florida under the September 21, 2009, Federal order on citrus greening, which prohibits the interstate movement of plants and plant parts other than fruit from species that are hosts of citrus greening.

Regulatory Impact Analysis

Addressing the preliminary regulatory impact analysis and initial regulatory flexibility analysis we prepared for the proposed rule, two commenters stated that the document devotes almost 18 pages to the expected impacts of the proposed rule on the Florida industry. In the 2½ pages addressing the expected effects for the other commercial citrus-producing States, it is noted that APHIS expects “the primary effect of the rule would be to preserve Florida's fresh market in the long run.” The commenters noted that the analysis states that “...a reduction in the packout rate for fresh market fruit in the other commercial citrus-producing States due to citrus canker infestation would likely have a larger economic impact than has been experienced by Florida, due to their greater reliance on fresh citrus sales, especially of oranges.” The analysis also states that “in the event that citrus canker were to spread to other commercial citrus-producing States, we do not anticipate that other commercial citrus-producing States would find profitable alternative markets for fruit that could not be sold on the fresh market.” The commenters stated that this rule change is clearly for the benefit of the Florida citrus industry, and the interstate movement of citrus fruit from areas quarantined for citrus canker into commercial citrus-producing States should not be allowed

as the risks to the citrus industry in other commercial citrus-producing States are too high.

As discussed in the updated PRA and supplemental RMA, commercially packed and disinfected fresh citrus fruit is not an epidemiologically significant pathway for the introduction and spread of Xcc. We prohibit the interstate movement from a quarantined area of plants and plant products that are more likely pathways, such as grass clippings, plant clippings, tree clippings, and nursery stock, which (as other commenters noted) is the highest-risk pathway for the spread of citrus canker.

We acknowledge that citrus produced in other commercial citrus-producing States is produced primarily for the fresh market; for that reason, protecting the appearance of the fruit is critical for citrus production in for those States. We are committed to protecting against the spread of citrus canker to other commercial citrus-producing States, as evidenced by the mitigations required by the final rule for the interstate movement of fresh fruit from quarantined areas and the other movement restrictions in the regulations.

Consistent with the requirements of the Regulatory Flexibility Act (RFA), our preliminary regulatory impact analysis and initial regulatory flexibility analysis focused on any significant impacts the proposed rule could have on small entities. We determined that significant impacts on small entities, if they occur as a result of this final rule, are most likely to be experienced in Florida; the economic effects of allowing freer movement of Florida citrus are likely to be distributed among consumers in other States, as discussed.

Miscellaneous Change

We proposed to revise the definition of *commercial packinghouse* in § 301.75-1 to read: “An establishment in which space and equipment are maintained for the primary purpose of disinfecting and packing citrus fruit for commercial sale. A commercial packinghouse must also be licensed, registered, or certified with the State in which it operates and meet all the requirements for the license, registration, or certification that it holds.”

In this final rule, we are changing the proposed definition to indicate specifically in the second sentence that the commercial packinghouse must be licensed, registered, or certified for handling citrus fruit. The proposed definition could have been interpreted as referring to any type of license, registration, or certification; indicating

that the license, registration, or certification of a commercial packinghouse must be specifically for handling citrus fruit provides additional specificity and clarifies the intent of the definition.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, with the change discussed in this document.

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infected Satsuma mandarin fruit. *Crop Protection* 28:19-23.

Effective Date

This is a substantive rule that relieves restrictions and, pursuant to the provisions of 5 U.S.C. 553, may be made effective less than 30 days after publication in the **Federal Register**. Immediate implementation of this rule is necessary to provide relief to those persons who are adversely affected by restrictions we no longer find warranted. The shipping season for Florida citrus fruit is in progress. Making this rule effective immediately will allow interested producers and others in the marketing chain to benefit during this year's shipping season. Therefore, the Administrator of the Animal and Plant Health Inspection Service has determined that this rule should be effective upon publication in the **Federal Register**.

Executive Order 12866 and Regulatory Flexibility Act

This final rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

We have prepared an economic analysis for this rule. The economic analysis provides a cost-benefit analysis, as required by Executive Order 12866, and an analysis of the potential economic effects of this action on small entities, as required by the RFA. The economic analysis is summarized below. Copies of the full analysis are available on the Regulations.gov Web site (see footnote 1 in this document for a link to Regulations.gov) or by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

APHIS has determined that this final rule will continue to prevent the spread of citrus canker from quarantined areas while allowing the interstate movement of fruit and lessening the compliance burden associated with the fruit movement regulations. The rule will remove the risk of lot rejection of fresh fruit intended for interstate shipment solely because the fruit exhibits citrus canker symptoms, thereby supporting the long-term preservation of domestic fresh fruit markets for Florida's commercial packinghouses and growers. Fresh citrus fruit will no longer require diversion to other uses or markets because of citrus canker symptoms. In addition, APHIS is removing the current prohibition on the movement of Florida's fresh citrus fruit to other commercial citrus-producing States. We

do not anticipate that citrus production in these States will be significantly affected by Florida's market reentry.

While the lots rejected during the 2008-09 season were successfully diverted for processing or to fresh fruit markets within Florida or outside the United States, affected citrus producers and commercial packinghouses incurred revenue declines because of elimination charges and the lower prices received due to product diversion. The cost of producing citrus fruit intended for the fresh market is greater than the cost of production for the processed market, where the physical appearance of the fruit is not important.

Impact on Small Entities

The RFA requires that agencies consider the economic impact of rule changes on small businesses, organizations, and governmental jurisdictions. Section 605 of the RFA allows an agency to certify a rule if the proposed rulemaking will not have a significant economic impact on a substantial number of small entities. Following is the factual basis for such certification in this case.

Based on the determination that fresh citrus fruit treated using an APHIS-approved disinfectant is not an epidemiologically significant pathway for transmission of the disease, this final rule will remove the requirement of an APHIS inspection of fresh packed citrus intended for the domestic market for symptoms of citrus canker disease. The final rule will require the treatment of fresh citrus from a commercial packinghouse with an APHIS-approved disinfectant. The final rule will relieve prohibitions associated with the current limited permit requirement, and allow the reentry of fresh citrus fruit from Florida into other commercial citrus-producing States. This action is being taken to relieve restrictions on the Florida citrus industry that we believe are no longer warranted while continuing to prevent the spread of citrus canker to other commercial citrus-producing States and territories.

Florida's citrus commercial packinghouses and fresh citrus producers comprise the industries that will be directly affected by this final rule. The small business size standard for citrus fruit packing, as identified by the Small Business Administration (SBA) based upon the North American Industry Classification System (NAICS) code 115114 (Postharvest Crop Activities) is \$6.5 million or less in annual receipts. There are currently 174 commercial packinghouses in Florida under APHIS Packinghouse Compliance Agreements, 56 of which are registered

with the Florida Department of Agriculture and Consumer Services' Division of Fruit and Vegetables. While the classification of all of these establishments by sales volume is not available, it is estimated that approximately 40 of the 56 registered commercial packinghouses are the top-grossing citrus commercial packinghouses. The remaining packinghouses are small establishments known primarily as gift packers. At least 95 percent of Florida fresh citrus shipments are packed by the top 40 (23 percent) commercial packinghouses in the State.⁴ The Fresh Shippers Report, as reported by the Citrus Administrative Committee, details quantities of fresh citrus shipped by the top 40 shippers each season.⁵ During the 2007-08 season, annual sales for 14 of the top 40 shippers (35 percent) were below the SBA size standard of \$6.5 million. It is estimated that at least 82 percent of Florida's citrus packers, including the small gift packers, will be considered small according to the SBA size standards.

The final rule is also expected to positively affect producers of fresh citrus in Florida currently facing an increasing number of lots rejected at the packinghouse level each season. Packing and elimination charges for growers are higher for fruit diverted to the within-State or export markets, or to processing plants. In addition, fruit diverted to processing yields lower revenues for growers who have already borne the higher costs of producing fruit intended for the fresh market.

A majority of the Florida citrus producers that will be affected by the final rule are small, based on 2007 Census of Agriculture data and SBA guidelines for entities classified within the farm categories Orange Groves (NAICS 111310) and Citrus (except Orange) Groves (NAICS 111320). SBA classifies producers in these categories with total annual sales of not more than \$750,000 as small entities. According to 2007 Census data, there were a total of 6,061 citrus farms in Florida in 2007. Of this number, 90 percent had annual sales in 2007 of less than \$500,000, which is well below the SBA's small-entity threshold of \$750,000.⁶ Any costs associated with the final rule are expected to be minimal, especially given the producers' gains from fewer

⁴ "Fresh Shippers Report: 2007-08 Season Through July 31, 2008," Citrus Administrative Committee, August 8, 2008. (<http://www.citrusadministrativecommittee.org/>)

⁵ Ibid.

⁶ Source: SBA and 2007 Census of Agriculture.

rejections of fresh citrus lots destined for the domestic market.

Producers of fresh fruit in other commercial citrus-producing States may also be impacted by the rule to the extent that the reintroduction of Florida fresh citrus changes the supply in these States. However, APHIS does not anticipate significant increases in fresh citrus supplies into these markets as a result of this final rule as indicated by historic data on Florida fresh citrus shipments. According to 2007 Census data, there were a total of 15,658 citrus farms in the United States in 2007. Of this total, 329 were located in Arizona, 7,358 in California, 884 in Hawaii, 210 in Louisiana, and 750 in Texas. In each State, at least 91 percent of all farms had annual sales in 2007 of less than \$500,000 and are classified as small entities according to SBA guidelines.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

National Environmental Policy Act

An environmental assessment and finding of no significant impact have been prepared for this final rule. The environmental assessment provides a basis for the conclusion that the interstate movement of citrus fruit under the conditions specified in this rule will not have a significant impact on the quality of the human environment. Based on the finding of no significant impact, the Administrator of the Animal and Plant Health Inspection Service has determined that an environmental impact statement need not be prepared.

The environmental assessment and finding of no significant impact were prepared in accordance with: (1) The National Environmental Policy Act of

1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500-1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

The environmental assessment and finding of no significant impact may be viewed on the Regulations.gov Web site.⁷ Copies of the environmental assessment and finding of no significant impact are also available for public inspection at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect copies are requested to call ahead on (202) 690-2817 to facilitate entry into the reading room. In addition, copies may be obtained by writing to the individual listed under **FOR FURTHER INFORMATION CONTACT.**

Paperwork Reduction Act

This final rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 7 CFR Part 301

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

■ Accordingly, we are amending 7 CFR part 301 as follows:

PART 301—DOMESTIC QUARANTINE NOTICES

■ 1. The authority citation for part 301 continues to read as follows:

Authority: 7 U.S.C. 7701-7772 and 7781-7786; 7 CFR 2.22, 2.80, and 371.3.

Section 301.75-15 issued under Sec. 204, Title II, Public Law 106-113, 113 Stat. 1501A-293; sections 301.75-15 and 301.75-16 issued under Sec. 203, Title II, Public Law 106-224, 114 Stat. 400 (7 U.S.C. 1421 note).

■ 2. In § 301.75-1, the definition of *commercial packinghouse* is revised to read as follows:

§ 301.75-1 Definitions.

* * * * *

Commercial packinghouse. An establishment in which space and equipment are maintained for the

primary purpose of disinfecting and packing citrus fruit for commercial sale. A commercial packinghouse must also be licensed, registered, or certified for handling citrus fruit with the State in which it operates and meet all the requirements for the license, registration, or certification that it holds.

* * * * *

§ 301.75-4 [Amended]

■ 3. Section 301.75-4 is amended as follows:

■ a. In paragraph (d)(2)(ii)(D), by removing the first sentence.

■ b. By removing paragraph (d)(6).

■ 4. Section 301.75-7 is revised to read as follows:

§301.75-7 Interstate movement of regulated fruit from a quarantined area.

(a) Regulated fruit produced in a quarantined area or moved into a quarantined area for packing may be moved interstate with a certificate issued and attached in accordance with § 301.75-12 if all of the following conditions are met:

(1) The regulated fruit was packed in a commercial packinghouse whose owner or operator has entered into a compliance agreement with APHIS in accordance with § 301.75-13.

(2) The regulated fruit was treated in accordance with § 301.75-11(a).

(3) The regulated fruit is free of leaves, twigs, and other plant parts, except for stems that are less than 1 inch long and attached to the fruit.

(4) If the fruit is repackaged after being packed in a commercial packinghouse and before it is moved interstate from the quarantined area, the person that repackages the fruit must enter into a compliance agreement with APHIS in accordance with § 301.75-13 and issue and attach a certificate for the interstate movement of the fruit in accordance with § 301.75-12.

(b) Regulated fruit that is not eligible for movement under paragraph (a) of this section may be moved interstate only for immediate export. The regulated fruit must be accompanied by a limited permit issued in accordance with § 301.75-12 and must be moved in a container sealed by APHIS directly to the port of export in accordance with the conditions of the limited permit.

(Approved by the Office of Management and Budget under control number 0579-0325)

⁷ Go to (<http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2009-0023>). The environmental assessment and finding of no significant impact will appear in the resulting list of documents.

Done in Washington, DC, this 15th day of October 2009.

Kevin Shea

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E9-25328 Filed 10-21-09; 8:45 am]

BILLING CODE 3410-34-S

DEPARTMENT OF ENERGY

10 CFR Part 430

[Docket No. EERE-2008-BT-TP-0007]

RIN 1904-AB77

Energy Conservation Program: Test Procedures for Fluorescent Lamp Ballasts (Standby Mode)

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Final rule.

SUMMARY: The U.S. Department of Energy (DOE) is amending its test procedures for fluorescent lamp ballasts under the Energy Policy and Conservation Act. These amendments address the measurement of energy consumption of fluorescent lamp ballasts in the standby mode. These amendments do not address energy consumption in off mode, because DOE has determined that these products do not operate in off mode.

DATES: This rule is effective November 23, 2009. The incorporation by reference of certain publications listed in this rule was approved by the Director of the Federal Register on November 23, 2009.

ADDRESSES: You may review copies of all materials related to this rulemaking at the U.S. Department of Energy, Resource Room of the Building Technologies Program, 950 L'Enfant Plaza, SW., Suite 600, Washington, DC, (202) 586-2945, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays. Please call Ms. Brenda Edwards at the above telephone number for additional information regarding visiting the Resource Room.

FOR FURTHER INFORMATION CONTACT: Ms. Linda Graves, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Program, EE-2J, 1000 Independence Avenue, SW., Washington, DC 20585-0121. Telephone: (202) 586-1851. E-mail: Linda.Graves@ee.doe.gov.

Mr. Eric Stas, U.S. Department of Energy, Office of the General Counsel, GC-72, 1000 Independence Avenue, SW., Washington, DC 20585. Telephone:

(202) 586-5827. E-mail: Eric.Stas@hq.doe.gov.

SUPPLEMENTARY INFORMATION: This final rule incorporates by reference into Appendix Q of Subpart B of Title 10, Code of Federal Regulations, part 430, the following industry standards from the American National Standards Institute (ANSI):

1. ANSI Standard C82.2-1984, Revision of ANSI C82.2-1977 "American National Standard for Lamp Ballasts—Methods of Measurement," October 21, 1983; and

2. ANSI Standard C82.2-2002, Revision of ANSI C82.2-1994 (R1995) "American National Standard for Lamp Ballasts—Methods of Measurement of Fluorescent Lamp Ballasts," June 6, 2002.

Copies of the ANSI standards can be obtained from the American National Standards Institute, 25 W. 43rd Street, 4th Floor, New York, NY 10036, (212) 642-4900, or <http://www.ansi.org>. One can also view a copy of these standards at the U.S. Department of Energy, Resource Room of the Building Technologies Program, 950 L'Enfant Plaza, SW., 6th Floor, Washington, DC 20024, (202) 586-2945, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

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I. Authority and Background

Title III of the Energy Policy and Conservation Act (42 U.S.C. 6291 *et seq.*; EPCA or the Act) sets forth a variety of provisions designed to improve energy efficiency. Part A¹ of Title III (42 U.S.C. 6291-6309) establishes the "Energy Conservation Program for Consumer Products Other Than Automobiles," which covers consumer products (all of which are referred to below as "covered products"), including fluorescent lamp ballasts (ballasts). (42 U.S.C. 6291(1)-(2) and 6292(a)(13))

The program consists essentially of testing, labeling, and Federal energy conservation standards. The testing requirements consist of test procedures that manufacturers of covered products must use as the basis for certifying to DOE that their products comply with EPCA energy conservation standards and for representing the energy efficiency of their products.

Section 323(b) of EPCA (42 U.S.C. 6293 (b)) authorizes DOE to amend or establish new test procedures as appropriate for each covered product. It states that "[a]ny test procedures prescribed or amended under this section shall be reasonably designed to produce test results which measure energy efficiency, energy use, * * * or estimated annual operating cost of a covered product during a representative average use cycle or period of use, as determined by the Secretary [of Energy], and shall not be unduly burdensome to conduct." (42 U.S.C. 6293(b)(3)) In addition, EPCA states that DOE "shall determine, in the rulemaking carried out with respect to prescribing such procedure, to what extent, if any, the proposed test procedure would alter the measured energy efficiency * * * of any covered product as determined under the existing test procedure." (42 U.S.C. 6293(e)(1)) If DOE determines that the amended test procedure would alter the measured efficiency of a covered product, DOE must amend the applicable energy conservation standard accordingly. (42 U.S.C. 6293(e)(2))

For ballasts, the test procedures must be "in accord with ANSI Standard C82.2-1984 or other test procedures determined appropriate by the Secretary." (42 U.S.C. 6293(b)(5)) DOE's existing test procedures for ballasts, adopted pursuant to the above provisions, appear at Title 10 of the Code of Federal Regulations (CFR) part 430, subpart B, appendix Q ("Uniform

¹ For editorial reasons, Part B (Consumer Products) and Part C (Commercial Equipment) of Title III of EPCA were redesignated as Parts A and A-1, respectively, in the United States Code.

Test Method for Measuring the Energy Consumption of Fluorescent Lamp Ballasts”).

The Energy Independence and Security Act of 2007 (Pub. L. 110–140; EISA 2007) was enacted December 19, 2007, and contains numerous amendments to EPCA. These include a requirement that DOE must amend the test procedures to include standby mode and off mode energy consumption in the overall energy efficiency, energy consumption, or other energy descriptor for each covered product for which DOE’s current test procedures do not fully account for standby mode and off mode energy consumption. If that is technically infeasible, DOE must prescribe a separate standby mode and off mode energy use test procedure, if technically feasible. (42 U.S.C. 6295(gg)(2)(A)) Any such amendment must consider the most current versions of International Electrotechnical Commission (IEC) Standards 62301 and 62087. *Id.*

In a separate rulemaking proceeding, DOE is considering energy conservation standards for fluorescent lamp ballasts (docket number EERE–2007–BT–STD–0016; hereafter referred to as the “ballast standards rulemaking”). DOE initiated that rulemaking by publishing a **Federal Register** notice announcing a public meeting and availability of the Framework Document (“Energy Efficiency Program for Consumer Products: Public Meeting and Availability of the Framework Document for Fluorescent Lamp Ballasts”) on January 22, 2008. 73 FR 3653. One issue DOE raised for comment in the ballast standards rulemaking Framework Document related to DOE’s obligation to develop a test procedure that measures the energy consumed by fluorescent lamp ballasts in standby mode and off mode. DOE received comments on this issue from interested parties, both orally at the February 6, 2008 Framework public meeting and in writing, and DOE addressed these comments in a notice of proposed rulemaking (NOPR) for the test procedure published on January 21, 2009. 74 FR 3450 (hereafter the “January 2009 NOPR”). DOE presented and explained the test procedure proposed rule and received oral comments at a public meeting on February 2, 2009. DOE invited written comments, data, and other information on the January 2009 NOPR and accepted such material through April 6, 2009. *Id.*

The amendments contained in section 310(3) of EISA 2007 insert a new subsection (gg)(3) into section 325 of EPCA, which in part directs that any final rule establishing or revising a

standard for a covered product adopted after July 1, 2010, shall address standby mode and off mode energy use. (42 U.S.C. 6295(gg)(3)) However, pursuant to new section 325(gg)(2)(C) of EPCA (42 U.S.C. 6295(gg)(2)(C)), the amendments for the test procedure will not apply to the existing energy conservation standards for fluorescent lamp ballasts. Instead, the test procedure described in today’s final rule will lay the groundwork for DOE to measure and consider energy consumed in standby mode and off mode for the ballast standards rulemaking (scheduled to be completed in 2011) and future rulemakings. This test procedure will also provide a means for determining compliance with any energy conservation standard for fluorescent lamp ballasts which DOE adopts that includes such energy consumption.

II. Summary of the Final Rule

In this final rule, DOE is modifying the current test procedures for fluorescent lamp ballasts to incorporate a measure of standby mode and off mode energy consumption, as required by section 310 of EISA 2007.

In the context of fluorescent lamp ballasts, DOE reviewed the definitions of “standby mode” and “off mode” contained in EPCA section 325(gg)(1). (42 U.S.C. 6295(gg)(1)) DOE found that while it is possible for fluorescent lamp ballasts to operate in standby mode, the off mode condition does not apply to fluorescent lamp ballasts because they do not operate in this mode. For this reason, today’s final rule prescribes a test method for measuring power consumed in standby mode (*see* section III.C), but does not prescribe any off mode test method.

Because no standby mode energy conservation standard for fluorescent lamp ballasts currently exists, the introductory sentence in subsection 2.2 of appendix Q to subpart B of part 430 prescribed by this final rule states that “[t]he measurement of standby mode power need not be performed to determine compliance with energy conservation standards for fluorescent lamp ballasts at this time. The above statement will be removed as part of the rulemaking to amend the energy conservation standards for fluorescent lamp ballasts to account for standby mode energy consumption, and the following shall apply on the compliance date for such requirements.” Although its application is not currently required, the test method prescribed by this final rule will enable DOE to consider the development of standby mode energy consumption requirements in the

context of the fluorescent lamp ballast standards rulemaking.

As explained in the January 2009 NOPR, the definition of “standby mode” created by EISA 2007 does not apply to all ballasts. 74 FR 3450, 3456 (Jan. 21, 2009). Therefore, DOE proposed test procedure amendments for standby mode that would apply only to certain ballasts under certain operating conditions. *See* sections III.A and III.B for a detailed discussion of the definitions for “standby mode” and “off mode” and of the proposed test procedures for standby mode.

The amendments contained in this final rule are based on provisions contained in and adapted from the current ANSI testing standard, ANSI Standard C82.2–2002. DOE’s existing test procedure for fluorescent lamp ballasts measures the input power for active mode using ANSI Standard C82.2–1984, as contained in 10 CFR part 430, subpart B, appendix Q, “Uniform Test Method for Measuring the Energy Consumption of Fluorescent Lamp Ballasts.” However, the amendments contained in this final rule are based on measuring input power for the standby mode test procedure using ANSI Standard C82.2–2002, the most current version of that standard. The only difference between the two test procedures relates to the interference of testing instrumentation. Specifically, the input power measurement of C82.2–2002 reduces the interference of instrumentation on the input power measurement as compared to C82.2–1984. However, because modern instrumentation does not significantly interfere with input power measurements, DOE understands that the differences between the input power measurements of the two test procedures are negligible.

At this time, DOE is not updating the fluorescent lamp ballast active mode test procedure references of ANSI Standard C82.2–1984 because DOE intends to consider revising the fluorescent lamp ballast active mode test procedure in a subsequent rulemaking, as discussed on pages 7 through 9 of the framework document and at the Framework Document public meeting in the ballast standards rulemaking. (Public Meeting Transcript, No. 9 at p. 70)²

² A notation in the form “Public Meeting Transcript, No. 9 at pp. 11–12 and 69–78” identifies a written comment that DOE has received and has included in the docket of a rulemaking. This particular notation refers to a comment: (1) Submitted during the public meeting on February 6, 2008; (2) in document number 9 in the docket of this rulemaking; and (3) appearing on page 70 of the transcript. In particular, this comment is found

As discussed above, EPCA requires that DOE determine to what extent, if any, the proposed test procedure would alter the measured energy efficiency of a covered product as determined under the current test procedure. (42 U.S.C. 6293(e)(1)) The amendments contained in today's final rule only add provisions to sections 1, 2, and 3 of appendix Q to subpart B of Part 430 to address new definitions, test conditions, and methods for measuring standby mode power. These amendments do not affect the existing active mode test procedure or energy conservation standards in place for fluorescent lamp ballasts, because: (1) The existing active mode test procedures are separate from and can be applied independent of the standby mode test procedure provisions; (2) the current energy conservation standards for fluorescent lamp ballasts do not address standby mode energy consumption; and (3) the standby mode test procedure requirements do not apply until the compliance date set forth in the final rule amending the energy conservation standards for fluorescent lamp ballasts to account for standby mode energy consumption (anticipated in 2011). Thus, the test procedure amendments contained in this final rule will not change the measurement of the ballast efficacy factor, the metric on which the current energy conservation standard is based. In addition, EISA 2007 provides that amendments to the test procedures to include standby mode and off mode energy consumption shall not be used to determine compliance with previously established standards. (42 U.S.C. 6295(gg)(2)(C)) Thus, inclusion of the standby mode provisions in today's final rule amending DOE's fluorescent lamp ballast test procedures will not alter the measured fluorescent lamp ballast energy efficiency and will not affect a manufacturer's ability to demonstrate compliance with the existing energy conservation standards for fluorescent lamp ballasts. Based on the circumstances described above, DOE believes that the EPCA requirement to address whether a test procedure amendment would alter the measured efficiency of a product (thereby requiring amendment of existing standards) has been satisfied and that no further amendments are necessary. DOE notes that any representation regarding fluorescent lamp ballast standby mode energy use (such as in manufacturer marketing literature) must be based on the test procedure prescribed in this

final rule after it becomes effective. DOE is currently unaware, however, of any manufacturer making such representations. Thus, DOE believes that the test procedure in itself will have little (if any) impact on manufacturers unless and until DOE establishes efficiency standards addressing standby mode energy consumption in the fluorescent ballast standards final rule.

The final rule also amends the regulations to conform to format requirements regarding the incorporation by reference of the ANSI standards.

III. Discussion

A. Definitions

In the January 2009 NOPR, DOE proposed that only active mode and standby mode operation are applicable to fluorescent lamp ballasts. DOE also proposed that off mode does not exist for a ballast. 74 FR 3450, 3453 (Jan. 21, 2009). As discussed below, this position remains valid for today's final rule.

1. Active Mode

Although DOE is not directed to adopt a test procedure for active mode in section 325(gg) of EPCA, a review of the definition of "active mode" and DOE's interpretation of its meaning is necessary to clarify the definition of "off mode," which uses the term "active mode." EPCA section 325(gg)(1)(A)(i) defines "active mode" as "the condition in which an energy-using product—(I) is connected to a main power source; (II) has been activated; and (III) provides 1 or more main functions." (42 U.S.C. 6295(gg)(1)(A)(i)) In the January 2009 NOPR, DOE stated that the main function of a fluorescent lamp ballast is to operate one or more fluorescent lamps (*i.e.*, provide and regulate current to the lamps). 74 FR 3450, 3453 (Jan. 21, 2009). DOE also stated that the ballast is operating the lamp when the lamp is emitting any amount of light. *Id.*

In response to the January 2009 NOPR, the National Electrical Manufacturers Association (NEMA) questioned how DOE would treat ballasts subject to a "fault load," such as ballasts operating under conditions where it is not connected to a lamp, is connected to a failed lamp, or is connected to a faulty socket. (NEMA, No. 27 at p. 1) NEMA commented that this condition is not considered in the European Union (EU) definition of "standby mode" in Commission Regulation No. 1265/2008, which states: "'Standby mode(s)' means a condition where the equipment is connected to the mains power source, depends on energy input from the main power

source to work as intended and provides only the following functions, which may persist for an indefinite time:— Reactivation function, or reactivation function and only an indication of enabled reactivation function, and/or— information or status display;"

Commission Regulation (EC) No 1275/2008 of 17 December 2008, L 339/46 EN Official Journal of the European Union 18.12.2008. (NEMA, No. 27 at p. 2)

In amending its test procedures to account for standby mode and off mode energy consumption, Congress instructed DOE to take into account the current version of IEC 62301 (EISA 2007, section 310). DOE notes that the "standby mode" definition in IEC 62301 defines "standby mode" as the "lowest power consumption mode which cannot be switched off (influenced) by the user and that may persist for an indefinite time when an appliance is connected to the main electricity supply and used in accordance with the manufacturer's instructions." However, this IEC definition does not apply to a ballast connected to a "fault load," because connecting a ballast to a fault load is not using a ballast in accordance with the manufacturer's instructions. Similarly, while not controlling here, DOE agrees that ballasts connected to a fault load likewise do not meet the EU definition of "standby mode." DOE did not address the "fault load" condition in the NOPR.

Upon further consideration and in response to NEMA's comment, DOE believes a ballast that is connected to a "fault load" is in active mode. In fault mode, the ballast meets all three criteria for active mode function. More specifically, the ballast is activated, connected to mains power, and providing a main function. The main function of a ballast connected to a fault load is to apply a voltage across the sockets in an attempt to start and operate a lamp if a lamp were properly installed. Thus, DOE believes active mode for fluorescent ballasts is the condition in which the ballast is providing a regulated current to a properly installed functional lamp or providing a voltage to the sockets to start and operate a lamp if a functional lamp were properly installed. The above clarifies DOE's statement in the January 2009 NOPR regarding active mode operation of fluorescent lamp ballasts.

2. Standby Mode

EPCA section 325(gg)(1)(A)(iii) defines "standby mode" as "the condition in which an energy-using product—(I) is connected to a main power source; and (II) offers 1 or more of the following user-oriented or

in the docket for the fluorescent lamp ballast energy conservation standards rulemaking (Docket No. EERE-2007-BT-STD-0016, RIN: 1904-AB50).

protective functions: (aa) To facilitate the activation or deactivation of other functions (including active mode) by remote switch (including remote control), internal sensor, or timer. (bb) Continuous functions, including information or status displays (including clocks) or sensor-based functions.” (42 U.S.C. 6295(gg)(1)(A)(iii))

As described below, two key aspects of this definition are that fluorescent lamp ballasts must: (1) Be connected to a main power source, and (2) offer the activation or deactivation of other functions by remote switch or internal sensor.

To be in the “standby mode” under the EPCA definition of that term in part requires that fluorescent lamp ballasts be connected to their main power source. (42 U.S.C. 6295(gg)(1)(A)(iii)) This requirement effectively precludes the majority of ballasts from having standby mode energy consumption, because most ballasts are operated with on-off switches, motion sensors, circuit breakers, or other relays that connect main power to switch on the ballast. Once the main power source is connected to the ballast, the ballast immediately begins to provide voltage to the lamp sockets to start a lamp (if a functional lamp were properly installed) and then to provide a regulated current to a properly-installed, functional lamp. In this way, the ballast is in active mode, as discussed above. Thus, DOE finds that those ballasts that are controlled by disconnecting the main power source from the ballast never operate in standby mode.

EPCA’s definition of “standby mode” also applies to energy-using products that facilitate the activation or deactivation of other functions by remote switch, internal sensor, or timer. (42 U.S.C. 6295(gg)(1)(A)(iii)(II)(aa)) DOE interprets this condition as applying only to fluorescent lamp ballasts that are designed to operate in, or function as, a lighting control system where auxiliary control devices send signals to the ballast. An example would be a ballast that incorporates a digital addressable lighting interface (DALI). A ballast that incorporates a lighting interface like DALI (whether dimming or not) has an electronic circuit enabling the ballast to communicate with, and receive instructions from, the lighting interface. These instructions could tell the ballast to enter active mode or to adjust the light output to zero-percent output. In the latter case, the ballast no longer provides a regulated voltage and/or current to its sockets. Moreover, such ballasts are always connected to a main power source without being disconnected by an on-off switch or

other type of relay. Thus, at zero light output, the ballast is standing by, connected to a main power source while it awaits instructions from the lighting control system to provide regulated voltage and/or current to its sockets. Thus, the only fluorescent lamp ballasts DOE is aware of that meet the statutory requirements for standby mode are those ballasts that are an active component of a lighting control system. DOE did not receive any adverse comments with regard to its interpretation of “standby mode” for fluorescent ballasts. Therefore, in consideration of the above, DOE’s interpretation of standby mode remains the same as in the January 2009 NOPR. 74 FR 3450, 3453 (Jan. 21, 2009)

3. Off Mode

EPCA section 325(gg)(1)(A)(ii) defines “off mode” as “the condition in which an energy-using product—(I) is connected to a main power source; and (II) is not providing any standby or active mode function.” (42 U.S.C. 6295(gg)(1)(A)(ii)) DOE considered this definition in the context of fluorescent lamp ballasts and finds that off mode does not apply to any fluorescent lamp ballast (dimmable or non-dimmable), because off mode describes a condition that commercially-available ballasts do not attain.

The definition of “off mode” requires that ballasts be connected to a main power source and not provide any standby or active mode function. (42 U.S.C. 6295(gg)(1)(A)(ii)) It is not possible for ballasts to meet these criteria, because there is no condition in which the ballast is connected to the main power source and is not in a mode already accounted for in either active mode or standby mode (as defined previously). Thus, ballasts never meet the second requirement of the EPCA definition of “off mode.” (42 U.S.C. 6295(gg)(1)(A)(ii)(II)) DOE did not receive any adverse comments with regard to its interpretation of “off mode” for fluorescent ballasts. Therefore, DOE’s interpretation of “off mode” remains the same as in the January 2009 NOPR: that off mode is not applicable to fluorescent lamp ballasts. 74 FR 3450, 3453–54 (Jan. 21, 2009). Should circumstances change, DOE may revisit this interpretation and propose a test method for measuring off mode in fluorescent lamp ballasts.

B. Scope of Applicability

1. Types of Ballasts Covered

According to the definition set forth in 42 U.S.C. 6291(29)(A), “[t]he term ‘fluorescent lamp ballast’ means a

device which is used to start and operate fluorescent lamps by providing a starting voltage and current and limiting the current during normal operation.” This definition indicates that DOE’s coverage authority for this test procedure extends to many types of ballasts that are not covered by standards prescribed by EPCA, such as dimming ballasts. (42 U.S.C. 6295(g)(6); 42 U.S.C. 6295(g)(8)(C)) As discussed in section III.A.2 of this final rule, however, DOE considers standby mode as only applying to ballasts that incorporate some kind of lighting control system interface; DOE believes these ballasts are the only ones that currently satisfy the EPCA definition of “standby mode.” (42 U.S.C. 6295(gg)(1)(A)(iii)) These ballasts are designed with circuitry that adds features, including intelligent operation. As discussed in section III.A.2, one example of these ballasts would be a DALI-enabled ballast. DALI-enabled ballasts have internal circuitry that is fundamentally part of the ballast design that remains active and consumes energy, even when the ballast is not operating any lamps. DOE is unaware of any other types of ballasts that would perform standby mode functions.

In summary, although this test procedure applies to any “fluorescent lamp ballast” as defined in section 321 of EPCA (42 U.S.C. 6291(29)(A)), most ballasts would not be subject to the provisions pertaining to standby mode because they do not operate in the standby mode. DOE finds that the ballasts subject to standby mode power measurements would be those that incorporate some electronic circuit enabling the ballast to communicate with and be part of a lighting control system. Such ballasts could include both dimming ballasts and non-dimming ballasts. DOE did not receive any adverse comments with regard to its interpretation of the types of ballast covered by the standby mode test procedure provisions.

2. Relationship to Other Rulemakings

DOE is conducting two additional rulemakings on fluorescent lamp ballasts. As previously mentioned, DOE initiated a ballast standards rulemaking in January 2008, which will evaluate whether to amend the energy conservation standards in place for fluorescent lamp ballasts, including whether to add standby mode requirements. In that rulemaking process, DOE is also considering extending coverage and standards to additional fluorescent lamp ballasts, such as dimming ballasts. NEMA commented that this fluorescent lamp

ballast standby mode test procedure rulemaking may slow the market's adoption of dimming ballasts, which allow consumers to reduce light output and save energy. (NEMA, Public Meeting Transcript, No. 24 at pp. 34–35) DOE agrees that the majority of ballasts with a lighting control interface currently are dimming ballasts. Nevertheless, DOE notes that it is required by law to create a test procedure for fluorescent lamp ballasts in standby mode. (42 U.S.C. 6295(gg)(2)(A)) Furthermore, EPCA requires DOE to consider standby mode and off mode for all energy conservation standard final rules issued after July 1, 2010. (42 U.S.C. 6295(gg)(3)(A)) Because the final energy conservation standard rule for fluorescent lamp ballasts is scheduled to be issued in June 2011 (*i.e.*, after July 1, 2010), DOE must consider amending the standard to address standby mode during that rulemaking. DOE will carefully consider NEMA's comment regarding potential impacts on market adoption of dimming ballasts in the rulemaking amending the energy conservation standard to address standby mode energy consumption.

The second rulemaking is a test procedure rulemaking concerning fluorescent lamp ballast active mode energy consumption, in which DOE will consider updating the references to industry standards (found in appendix Q to subpart B of 10 CFR part 430) to current versions of the industry standards. EPCA requires that test procedures must be "in accord with ANSI standard C82.2–1984 or other test procedures determined appropriate by the Secretary." (42 U.S.C. 6293(b)(5)) Because the industry testing standard ANSI Standard C82.2 was revised in the year 2002, DOE is adopting ANSI Standard C82.2–2002 for measuring standby power for the test procedure amendments prescribed in this final rule. DOE notes that this will result in standby mode power measurement requirements that are different, at present, from those in the current active mode power test procedure, which references ANSI Standard C82.2–1984. However, DOE further notes that use of the standby mode provisions of the fluorescent lamp ballast test procedures is not required until the compliance date of an amended energy conservation standard that addresses standby mode operation, thereby further minimizing the impacts of referencing two different versions of the same ANSI standard.

C. Approach

1. Overview of Test Procedure

EPCA section 325(gg)(2)(A) in part directs DOE to establish test procedures to include standby mode, "taking into consideration the most current versions of Standards 62301 and 62087 of the International Electrotechnical Commission * * *" (42 U.S.C. 6295(gg)(2)(A)) IEC Standard 62087 applies only to audio, video, and related equipment, but not to lighting equipment. Thus, IEC Standard 62087 does not apply to this rulemaking, so DOE developed today's final rule consistent with procedures outlined in IEC Standard 62301, which applies generally to household electrical appliances. To develop a test method that would be familiar to fluorescent lamp ballast manufacturers, DOE referenced language and methodologies presented in ANSI Standard C82.2–2002, "For Lamp Ballasts—Method of Measurement of Fluorescent Lamp Ballasts."

Today's final rule test procedure for measuring standby mode energy consumption consists of the following steps: (1) A signal is sent to the ballast instructing it to reduce light output to zero percent; (2) the main input power to the ballast is measured; and (3) the power from the control signal path is measured in one or more of three ways, depending on how the signal from the control system is delivered to the ballast.

In sections III.C.2 through III.C.4, DOE discusses the amendments to section 1 of appendix Q to subpart B of 10 CFR part 430 (hereafter, "appendix Q").

2. Definitions

Section 1 of appendix Q provides definitions for terms used in the test procedure for fluorescent lamp ballasts. DOE is inserting five new terms to define terminology used in the test procedure amendments being adopted today: (1) AC control signal; (2) DC control signal; (3) PLC control signal; (4) standby power; and (5) wireless control signal. These new terms support the sections of the test procedure that address the measurement of control signal power to fluorescent lamp ballasts operating in standby mode. In addition, DOE is listing the terms in appendix Q alphabetically. The following text describes the origin of the five new terms. DOE did not receive any adverse comments with regard to the definitions proposed in the NOPR. Although DOE proposed in the NOPR to include a definition for "ANSI Standard C82.2–2002" in appendix Q, in this final rule, DOE has decided to provide

details regarding this incorporation by reference in 10 CFR 430.3, consistent with the formatting of other industry standards incorporated by reference.

The definition for "AC control signal" states that it is "an alternating current (AC) signal that is supplied to the ballast using additional wiring for the purpose of controlling the ballast and putting the ballast in standby mode." Some lighting control systems operate by communicating with the ballasts over a separate wiring system using an AC voltage. Neither IEC Standard 62301 nor ANSI Standard C82.2–2002 define "AC control signal." Therefore, DOE drafted the above definition of the term "AC control signal" to enhance the clarity and understanding of its test procedure—specifically that an AC control signal is a signal supplied to the ballast over a discrete wiring system for the purpose of ballast control. In today's test procedure final rule, DOE is requiring that the fluorescent lamp ballast's AC control signal power be measured through the control signal wiring system.

The definition of "DC control signal" states that it is "a direct current (DC) signal that is supplied to the ballast using additional wiring for the purpose of controlling the ballast and putting the ballast in standby mode." Some lighting control systems operate by communicating with the ballasts over a separate wiring system using DC voltage. DOE was unable to locate a definition for the term "DC control signal" in IEC Standard 62301 or ANSI Standard C82.2–2002. Therefore, DOE drafted the above definition of a "DC control signal" to enhance the clarity and understanding of its test procedure—specifically, that a DC control signal is a signal supplied to the ballast over a discrete wiring system for the purpose of ballast control. In today's test procedure final rule, DOE is requiring that the fluorescent lamp ballast's DC control signal power must be measured through the control signal wiring system.

The definition of "PLC control signal" states that it is "a power line carrier (PLC) signal that is supplied to the ballast using the input ballast wiring for the purpose of controlling the ballast and putting the ballast in standby mode." Some lighting control systems operate by communicating with the ballasts over the existing power lines that constitute the main power connection. DOE was unable to locate a definition for the term "PLC control signal" in IEC Standard 62301 or ANSI Standard C82.2–2002. Therefore, DOE drafted the above definition of a "PLC control signal" to enhance the clarity

and understanding of its test procedure—specifically, that a PLC control signal is a signal supplied to the ballast over the ballast's input power wiring for the purpose of controlling the ballast. In today's test procedure final rule, DOE is requiring that the fluorescent lamp ballast's PLC control signal power must be measured through the ballast input power wiring.

The definition of "standby mode" was provided in EPCA section 325(gg)(1)(A)(iii). (42 U.S.C. 6295(gg)(1)(A)(iii)) In today's final rule, DOE has decided to incorporate this EPCA definition into appendix Q.

The definition of "wireless control signal" states that it is "a wireless signal that is radiated to and received by the ballast for the purpose of controlling the ballast and putting the ballast in standby mode." Some lighting control systems operate by communicating with the ballasts over a wireless system, much like a wireless computer network. DOE was unable to locate a definition for the term "wireless control signal" in IEC Standard 62301 or ANSI Standard C82.2–2002. Therefore, DOE drafted the above definition of a "wireless control signal" to enhance the clarity and understanding of its test procedure—specifically, that a wireless control signal is a signal radiated from the lighting control system to the ballast for the purpose of controlling the ballast.

3. Test Conditions

Section 2 of appendix Q provides the required test conditions for measuring the performance of fluorescent lamp ballasts. DOE is modifying section 2 to establish new test conditions only for the measurement of standby mode energy consumption. This will not affect the existing test conditions required for measuring the ballast efficacy factor in the current fluorescent lamp ballast test procedure. Section 2 is now subdivided into two subsections, 2.1 and 2.2. Subsection 2.1 contains the same requirements previously in section 2, based on the test conditions contained in ANSI Standard C82.2–1984, for the purpose of measuring the ballast efficacy factor in active mode. Subsection 2.2 is structured in the same way as subsection 2.1; however, it is for the purpose of measuring energy consumed in standby mode, and the test conditions are based on ANSI Standard C82.2–2002. DOE acknowledges that the ANSI standards referenced in subsections 2.1 and 2.2 differ in areas related to the interference of testing instrumentation. Specifically, DOE believes the input power measurement of ANSI Standard C82.2–2002 reduces the interference of instrumentation on

the input power measurement as compared to ANSI Standard C82.2–1984. However, DOE also believes that because modern instrumentation does not significantly interfere with input power measurements, the differences between the input power measurements of the two test procedures are negligible. To address this difference and any other differences between the two ANSI standards, DOE will conduct a separate test procedure rulemaking on the existing (active mode) fluorescent lamp ballast test procedure; in that rulemaking, DOE will evaluate and consider updating the referenced ANSI standard in subsection 2.1. DOE will also evaluate and consider combining subsections 2.1 and 2.2 into one section.

The standby mode test procedure proposed by DOE in the January 2009 NOPR refers the reader to sections 5, 7, and 8 of ANSI Standard C82.2–2002 for all test conditions. These sections of the ANSI standard describe requirements for ballast electrical supply characteristics, test measurement circuits, and measurement instruments. The standard does not discuss configuration requirements for ballasts that can connect to control devices (sensors) or ballasts that can interface with circuitry for multiple types of control signals. NEMA commented that fluorescent lamp ballasts that can connect to control sensors do not represent the typical ballast configuration in a lighting system, and that the standby power of such ballasts should be measured with all control sensors disconnected from the ballast. (NEMA, No. 27 at p. 3) DOE acknowledges that the typical ballast installed in a lighting system may not have connections to control sensors and that a standby power measurement of a ballast with such devices attached will incorporate any energy that the ballast provides to these control sensors. DOE, however, interprets section 310(3) of EISA 2007 (42 U.S.C. 6295(gg)(2)) as requiring the establishment of a standby mode test procedure for all fluorescent lamp ballasts to which standby mode applies, because the statute does not limit coverage to only typical ballasts in lighting systems. Therefore, DOE is amending the fluorescent lamp ballast test procedure to cover ballasts in both typical and atypical configurations. Thus, DOE has added configuration requirements to section 2.2 of the test procedure, which now states that "[f]luorescent lamp ballasts that are capable of connections to control devices shall be tested with all commercially available compatible control devices connected in all

configurations supported by manufacturer literature. For each configuration, a separate measurement of standby power shall be made in accordance with section 3.5 of the test procedure." DOE believes that this revision enables the prescribed test procedure to characterize the maximum energy consumption of any fluorescent lamp ballast that features a standby mode.

DOE is also correcting the acronym used in existing section 2 for the American National Standard Institute, which is shown as "ANIS" instead of "ANSI." For clarity and also for consistency with other parts of the statute, DOE has also added two references to section 430.3 titled "Materials incorporated by reference" for information on obtaining ANSI Standard C82.2–1984 and ANSI Standard C82.2–2002. DOE notes that ANSI Standard C82.2–1984 is referenced by section 2.1 of the prescribed test procedure, while section 2.2 of the test procedure references ANSI Standard C82.2–2002. For clarity, all of section 2.1 is shown in this final rule notice as adopted new language, although the only actual changes to section 2.1 are the acronym correction, the reference to section 430.3, and the addition of a sentence that reads, "The test conditions described in this subsection (2.1) are applicable to subsections 3.3 and 3.4 of section 3, Test Method and Measurements."

4. Test Method and Measurements

Section 3 of appendix Q provides the test method and measurements associated with the fluorescent lamp ballast test procedure. This section references requirements for instrumentation and all the steps a technician must follow when measuring ballast performance. In today's final rule, DOE is not changing any of the existing requirements or steps associated with testing for determining the ballast efficacy factor. Instead, DOE is adding new steps at the end of section 3 that describe the procedure that must be followed for measuring energy consumed during ballast operation in standby mode.

In subsection 3.1, DOE is adding a new sentence: "The test for measuring standby mode energy consumption of fluorescent lamp ballasts shall be done in accordance with ANSI Standard C82.2–2002." DOE notes that the first sentence in subsection 3.1 states, "The test method for testing fluorescent lamp ballasts shall be done in accordance with ANSI Standard C82.2–1984." These two sentences in subsection 3.1 prescribed by this final rule create a

bifurcated test setup, requiring technicians to conduct the active mode testing on a fluorescent lamp ballast using conditions in ANSI Standard C82.2–1984 and then to test standby mode energy consumption using conditions in ANSI Standard C82.2–2002. However, DOE intends to initiate another fluorescent lamp ballast test procedure rulemaking that would consider the usage of one standard for all fluorescent lamp ballast energy consumption testing, for consistency and clarity. While today's test procedure will become effective 30 days after publication of this final rule, manufacturers will not be required to use the standby provisions of this test procedure to demonstrate compliance with the energy conservation standards for fluorescent lamp ballasts unless and until DOE amends the energy conservation standards to address standby mode energy consumption in a subsequent final rule which is scheduled to be completed in 2011, as explained in the January 2008 Framework Document for that rulemaking. 73 FR 3653, 3654 (Jan. 22, 2008). However, DOE notes that any representation regarding fluorescent lamp ballast standby mode energy use (such as in manufacturer marketing literature) must be based on the test procedure prescribed in this final rule after it becomes effective. DOE is currently unaware, however, of any manufacturer making such representations. Thus, DOE believes that the test procedure in itself will have little (if any) impact on manufacturers unless and until DOE establishes efficiency standards in the fluorescent ballast standards final rule.

In subsection 3.5, DOE has inserted the test method for measuring standby mode power. In this subsection, DOE directs the technician to send a signal to the ballast under test, instructing the ballast to have zero light output using the appropriate ballast communication protocol or system for that ballast. Next, the technician must measure the input power (in watts) to the ballast in accordance with ANSI Standard C82.2–2002. Finally, the technician measures the control signal power from the ballast control signal path using methods for all of the following signal path types that are applicable to the ballast: (1) An AC control signal path; (2) a DC control signal path; or (3) a power line carrier (PLC) control signal path, depending on the type of path or paths that the ballast employs.

The measurement of input power to the ballast from the main electricity supply is based on the approach in ANSI Standard C82.2–2002, section 13.

This measurement parallels the approach DOE followed in subsection 3.3.1 of the existing test procedure for fluorescent lamp ballasts, in which technicians are directed to measure the input power (watts) to the ballast in accordance with ANSI Standard C82.2–1984, section 3.2.1(3) and section 4. The requirements of ANSI Standard C82.2–1984 have been combined into section 13 in ANSI Standard C82.2–2002. Thus, the test measurements of ballast input power are required to be done in accordance with the appropriate sections of the industry test method.

NEMA commented on the measurement equipment in the ballast input power measurement method proposed in the January 2009 NOPR. NEMA expressed concern that the test procedure and a schematic shown at the public meeting could be interpreted as requiring the determination of input power to a ballast by separate measurements of voltage and current. NEMA requested clarification of the roles of the ammeter and volt-meter in the measurement of input power. (NEMA, No. 27 at p. 2) In response, DOE notes that the test procedure does not require the separate measurement of input power current and voltage. To clarify the test procedure measurement method, DOE has inserted revised schematics into sections 3.5.2, 3.5.3.1, and 3.5.3.3 of the test procedure that are based on the schematic shown in Figure 2 of section 7 in ANSI C82.2–2002. This figure indicates the presence of a power analyzer with internal wattage, voltage, and current measurement devices connected as shown in the schematic.

In subsection 3.5.3 of today's test procedure final rule, DOE requires a measurement of control signal power. DOE is aware of four possible ways to deliver a control signal to a fluorescent lamp ballast: (1) A dedicated AC control signal wire; (2) a dedicated DC control signal wire; (3) a PLC control signal over the main supply input wires; and (4) a wireless control signal. The test procedure requires measurement of the lighting control signal power and lists three methods for measuring that power, depending on which type of lighting control signal is used. DOE incorporates three circuit diagrams in sections 3.5.3.1, 3.5.3.2, and 3.5.3.3 to clearly present the method of measurement for each type of control system communication protocol.

The test procedure proposed in the January 2009 NOPR characterized fluorescent lamp ballasts featuring standby mode that utilized one type of control signal connection. It is technically feasible for a ballast to feature more than one type of control

signal connection. For this final rule, DOE has revised section 3.5.3 of the test procedure to indicate that “[t]he power from the control signal path will be measured using all applicable methods described” in sections 3.5.3.1 through 3.5.3.4 of the test procedure so that the procedure is capable of determining the maximum energy consumption of a fluorescent lamp ballast in standby mode.

As to the fourth approach, DOE estimates that the power supplied to a ballast using a wireless signal is well below 1.0 watt. NEMA agreed that for wireless control signals, the majority of the receiver power would be generated in the ballast, rather than being carried wirelessly to the ballast. (NEMA, Public Meeting Transcript, No. 24 at p. 28) DOE has excluded from the test procedure a measurement of wireless signal power for these reasons.

DOE received three other comments from interested parties on the measurement of control signal power. First, NEMA stated that equipment used to measure PLC power must be capable of measuring the appropriate frequencies, as the power distributed over the input ballast wiring would also include the PLC power. (NEMA, No. 27 at p. 2) DOE agrees with this comment and notes that section 3.5.3.3 of the test procedure requires the usage of a wattmeter of “a frequency response that is at least 10 times higher than the PLC being measured” in conjunction with a high-pass filter “to filter out power at 60 Hertz.” DOE believes that a high-pass-filtered wattmeter with such a frequency response will accurately measure the PLC signal; thus, DOE has made no change to the wattmeter requirements for PLC measurement in this final rule.

Second, the People's Republic of China (“P.R. China”) commented that DOE did not consider issues with electromagnetic compatibility (EMC) associated with the PLC signal in the January 2009 NOPR. P.R. China is concerned that electromagnetic interference from the PLC signal could significantly affect the measurement of standby power. (P.R. China, No. 26 at p. 2) DOE understands that if the PLC signal were a very high-frequency signal (e.g., with a frequency in the megahertz (MHz) range), then the electromagnetic interference from the signal would affect the standby power measurement significantly (i.e., cause variances in the input power measurement by more than one watt). However, PLC signals to fluorescent ballasts are on the order of 20 kilohertz (kHz). According to industry experts, any variance in the input power due to electromagnetic interference at frequencies of this

magnitude are insignificant (*i.e.*, variance would be much less than a watt). In fact, the Federal Communications Commission only regulates PLC measurements from 150 kHz to 30 MHz so that conducted emissions in this frequency range do not interfere with nearby radio receivers. (47 CFR 15 Subpart B) Accordingly, DOE has determined that shielding PLC measurements from electromagnetic interference for ballasts is unnecessary. As a result, DOE has not modified the test procedure to include shielding in today's final rule.

Third, NEMA commented on the intent of the circuit diagrams in sections 3.5.3.1, 3.5.3.2, and 3.5.3.3 of the test procedure regarding the measurement of control signal power. NEMA expressed concern that it is not clear that the intent of the circuit diagrams in sections 3.5.3.1, 3.5.3.2, and 3.5.3.3 is to measure only the control signal power to the ballast as opposed to the control system. (NEMA, Public Meeting Transcript, No. 24 at pp. 21–23) DOE believes that the intent of the diagrams (that only the control signal to the ballast should be measured) is clear, as they are similar to diagrams measuring the ballast input power in ANSI Standard C82.2–2002. Therefore, DOE has decided not to modify the circuit diagrams further for today's final rule.

NEMA also commented on the measurement of ballast input power and control signal power for ballasts that feature control signal device power supplies. NEMA commented that the measurement method proposed in the January 2009 NOPR is inappropriate for ballasts that use control devices powered by the ballast itself (*i.e.*, the power supply for the control sensors is built into the ballast), as the test procedure would measure the energy consumed by the control sensor power supply when the ballast is in standby mode. NEMA recommended that the ballast input power measurement method should apply only when the control device power supply is external to the ballast. NEMA commented that the proposed method would limit innovation by encouraging system designers to use control signal device power supplies separate from ballasts. (NEMA, No. 27 at p. 3) DOE agrees that the measurement method would measure the energy consumed by any control sensor power supply internal to a ballast when the ballast is in standby mode. The typical ballast in a lighting system may not have such power supplies; however, as explained previously, DOE interprets section 310(3) of EISA 2007 (42 U.S.C. 6295(gg)(2)) as requiring the

establishment of a standby mode test procedure for all fluorescent lamp ballasts that feature a standby mode, not only typical ballasts in lighting systems. It also would be burdensome to measure the energy consumed only by the elements of a ballast that are not related to the distribution of energy to control sensors, as such measurement would likely require the dismantling of a ballast. DOE will consider the impacts of fluorescent lamp ballast standby mode energy conservation standards on utility, consumers, the Nation, and other elements in the ballast standards rulemaking.

NEMA also suggested that the standby power of fluorescent lamp ballasts with internal control device power supplies should be determined solely by the input power measurement method. (NEMA, No. 27 at p. 3) DOE disagrees that only the input power measurement should be used for ballasts that feature control signal device power supplies. Because DOE's interest is energy savings for consumers and the Nation, DOE wishes to produce a test procedure that can determine the maximum energy consumption of a fluorescent lamp ballast in standby mode. This requires a measurement of ballast input power as well as control signal power of any control signal types that a ballast supports, regardless of whether the ballast features a control signal device power supply. Therefore, DOE has retained the test procedure's required measurements of control signal power and input power of a fluorescent lamp ballast in standby mode for this final rule.

5. Test Procedure Measurements and Burden

The fluorescent lamp ballast standby mode energy consumption test procedure prescribed in this final rule is consistent with IEC Standard 62301 and follows testing approaches used in ANSI Standard C82.2–2002. The procedure requires measurements of the input power of the ballast in standby mode and the control signal power of the ballast in standby mode, including measurements for all applicable control signal types and all manufacturer-supported configurations of control sensors connected to the ballast (according to manufacturer literature). DOE acknowledges that it does not indicate how to combine these measured values or use them in equations. DOE believes, however, that these measurements of standby mode power consumption will be necessary for the development of future energy conservation standards for fluorescent

lamp ballasts, and such issues will be addressed at that time, as necessary.

The test procedure prescribed in this final rule, as required by EPCA section 325(gg), is designed to produce results that measure power consumption in an accurate and repeatable manner, and should not be unduly burdensome on manufacturers to conduct, because it requires only one additional measurement using a test setup that is already commonly used in the industry for measuring ballast power consumption. Manufacturers are not currently required to measure standby mode power in order to determine compliance with energy conservation standards for fluorescent lamp ballasts, as the current energy conservation standards for such ballasts do not include a standby mode energy consumption requirement. However, DOE notes that any representation regarding fluorescent lamp ballast standby mode energy use (such as in manufacturer marketing literature) must be based on the test procedure prescribed in this final rule once it becomes effective. DOE is currently unaware, however, of any manufacturer making such representations. For these two reasons, DOE believes that today's test procedure amendments will have little (if any) impact on manufacturers unless and until DOE adopts fluorescent lamp ballast energy conservation standards that include standby mode energy consumption requirements. In addition, if DOE adopts such requirements, DOE believes that the test procedure adopted in this final rule would not be unduly burdensome. The amended test procedures requires a technician to make one additional measurement using a test setup that is already commonly used in the industry for measuring active mode ballast energy consumption. In addition, as stated in today's final rule, standby mode only applies to a very small subset of fluorescent lamp ballasts (*i.e.*, those enabled to operate on lighting control systems), and, therefore, the vast majority of ballasts sold would not be affected by today's amendments.

Concerning test procedure burden, NEMA commented that the test procedure proposed by DOE in the January 2009 NOPR adds workload to manufacturers for little or no benefit because DALI ballasts account for approximately 0.15 percent of ballast sales in the United States and are expected to remain low in sales volume over the next 5 years. (NEMA, No. 27 at p. 3) DOE is aware that the test procedure may add some incremental degree of burden to manufacturers. However, this rulemaking addresses the

creation of a test procedure for fluorescent lamp ballasts in standby mode, as required by section 310(3) of EISA 2007. (42 U.S.C. 6295(gg)(2)) The benefits of energy conservation standards will be characterized and quantified in the ballast standards rulemaking. For these reasons, DOE has continued with the creation of a test procedure for fluorescent lamp ballasts in standby mode. DOE has determined that the test procedure adopted in today's rulemaking is not unduly burdensome to conduct, as required by EPCA and discussed above. (42 U.S.C. 6293(b)(3))

IV. Regulatory Review

A. Executive Order 12866

Today's regulatory action is not a "significant regulatory action" under section 3(f) of Executive Order 12866, "Regulatory Planning and Review," 58 FR 51735 (Oct. 4, 1993). Accordingly, this action was not subject to review under that Executive Order by the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget (OMB).

B. National Environmental Policy Act

In this final rule, DOE is adopting the test procedure amendments that it expects will be used to develop and implement future energy conservation standards for fluorescent lamp ballasts. DOE has determined that this rule is covered under a class of actions categorically excluded from review under the National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. 4321 *et seq.*, and DOE's implementing regulations at 10 CFR part 1021. This rule amends an existing rule without changing its environmental effect, and, therefore, is covered by the Categorical Exclusion A5 found in appendix A to subpart D, 10 CFR part 1021. Accordingly, neither an environmental assessment nor an environmental impact statement is required.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires preparation of an initial regulatory flexibility analysis for any rule that by law must be proposed for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. As required by Executive Order 13272, "Proper Consideration of Small Entities in Agency Rulemaking," 67 FR 53461 (August 16, 2002), DOE published procedures and policies on February 19, 2003, to ensure that the potential

impacts of its rules on small entities are properly considered during the DOE rulemaking process. 68 FR 7990. DOE has made its procedures and policies available on the DOE Office of the General Counsel's Web site (<http://www.gc.doe.gov>).

DOE reviewed today's final rule under the provisions of the Regulatory Flexibility Act and the policies and procedures published on February 19, 2003. DOE certified in the January 2009 NOPR that the proposed rule would not have a significant impact on a substantial number of small entities. 74 FR 3450, 3457 (Jan. 21, 2009). As part of this rulemaking, DOE examined the existing compliance costs manufacturers already bear and compared them to the revised compliance costs, based on the proposed revisions to the test procedure. While it is true that manufacturers making any public representation of the standby power consumption of their ballasts would be required to use this test procedure, DOE does not find that the burden imposed by the revisions in this document would result in any significant increase in testing or compliance costs. Rather, the technician is required to make one additional measurement using a test setup that is already commonly used in the industry for measuring ballast power consumption. In addition, as stated in today's final rule, standby mode only applies to a very small subset of fluorescent lamp ballasts (*i.e.*, those enabled to operate on lighting control systems), and, therefore, the vast majority of ballasts sold would not be affected by today's test procedure amendments. Accordingly, DOE has not prepared a regulatory flexibility analysis for this rulemaking. DOE's certification and supporting statement of factual basis are provided again in this notice to the Chief Counsel for Advocacy of the Small Business Administration pursuant to 5 U.S.C. 605(b).

DOE did not receive any comments addressing small business impacts for manufacturers of fluorescent lamp ballasts. Thus, DOE reaffirms and certifies that this rule will have no significant economic impact on a substantial number of small entities.

D. Paperwork Reduction Act

This rule contains a collection-of-information requirement subject to the Paperwork Reduction Act (PRA) which has been approved by OMB under control number 1910-1400. Public reporting burden for compliance reporting for energy and water conservation standards is estimated to average 30 hours per response, including the time for reviewing

instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate, or any other aspect of this data collection, including suggestions for reducing the burden, to DOE (*see ADDRESSES*) and by e-mail to Christine.J.Kymn@omb.eop.gov.

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.

E. Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4; UMRA) requires each Federal agency to assess the effects of Federal regulatory actions on State, local, and Tribal governments and the private sector. Subsection 101(5) of title I of that law defines a Federal intergovernmental mandate to include any regulation that would impose on State, local, or Tribal governments an enforceable duty, except a condition of Federal assistance or a duty arising from participating in a voluntary Federal program. For proposed regulatory actions likely to result in a rule that may cause expenditures by State, local, and Tribal governments, in the aggregate, or by the private sector of \$100 million or more in any one year (adjusted annually for inflation), section 202 of UMRA requires Federal agencies to publish estimates of the resulting costs, benefits, and other effects on the national economy (2 U.S.C. 1532(a), (b)). UMRA also requires Federal agencies to develop an effective process to permit timely input by elected officers of State, local, and Tribal governments on a proposed "significant intergovernmental mandate." UMRA also requires an agency plan for giving notice and opportunity for timely input to small governments that may be affected before establishing a requirement that might significantly or uniquely affect them. On March 18, 1997, DOE published a statement of policy on its process for intergovernmental consultation under UMRA. 62 FR 12820. (This policy is also available at <http://www.gc.doe.gov>.) Today's final rule contains neither an intergovernmental mandate, nor a mandate that may result in the expenditure of \$100 million or more in any year. Accordingly, no further assessment or analysis is required under

the Unfunded Mandates Reform Act of 1995.

F. Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105–277; 5 U.S.C. 601 note) requires Federal agencies to issue a Family Policymaking Assessment for any rule that may affect family well-being. Today's rule would not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is unnecessary to prepare a Family Policymaking Assessment.

G. Executive Order 13132

Executive Order 13132, "Federalism," 64 FR 43255 (August 10, 1999) imposes certain requirements on agencies formulating and implementing policies or regulations that preempt State law or that have Federalism implications. The Executive Order requires agencies to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and to carefully assess the necessity for such actions. The Executive Order also requires agencies to have an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have Federalism implications. On March 14, 2000, DOE published a statement of policy describing the intergovernmental consultation process it will follow in the development of such regulations. 65 FR 13735. DOE has examined this final rule and has determined that it 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. Accordingly, no further action is required under Executive Order 13132.

H. Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, "Civil Justice Reform," 61 FR 4729 (Feb. 7, 1996) imposes on Federal agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; (3) provide a clear legal standard for affected conduct rather than a general standard; and (4) promote simplification and burden reduction. Section 3(b) of Executive Order 12988 specifically

requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in sections 3(a) and 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, this rule meets the relevant standards of Executive Order 12988.

I. Treasury and General Government Appropriations Act, 2001

Section 515 of the Treasury and General Government Appropriations Act, 2001 (Pub. L. 106–554; 44 U.S.C. 3516 note) provides for agencies to review most disseminations of information to the public under guidelines established by each agency pursuant to general guidelines issued by OMB. OMB's guidelines were published at 67 FR 8452 (Feb. 22, 2002), and DOE's guidelines were published at 67 FR 62446 (Oct. 7, 2002). DOE has reviewed today's rule under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

J. Executive Order 13211

Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use," 66 FR 28355 (May 22, 2001) requires Federal agencies to prepare and submit to OMB, a Statement of Energy Effects for any proposed significant energy action. A "significant energy action" is defined as any action by an agency that promulgates or is expected to lead to promulgation of a final rule, and that: (1) Is a significant regulatory action under Executive Order 12866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (3) is designated by the Administrator of OIRA as a significant energy action. For any proposed significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use

should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use. Today's regulatory action is not a significant regulatory action under Executive Order 12866. Moreover, it would not have a significant adverse effect on the supply, distribution, or use of energy. It has likewise not been designated by the Administrator of OIRA as a significant energy action. Therefore, it is not a significant energy action, and, accordingly, DOE has not prepared a Statement of Energy Effects.

K. Executive Order 12630

Pursuant to Executive Order 12630, "Governmental Actions and Interference with Constitutionally Protected Property Rights," 53 FR 8859 (March 15, 1988), DOE has determined that this rule would not result in any takings that might require compensation under the Fifth Amendment to the U.S. Constitution.

L. Section 32 of the Federal Energy Administration Act of 1974

Under section 301 of the Department of Energy Organization Act (Pub. L. 95–91; 42 U.S.C. 7101), DOE must comply with section 32 of the Federal Energy Administration Act of 1974, as amended by the Federal Energy Administration Authorization Act of 1977 (15 U.S.C. 788; FEAA). Section 32 essentially provides in part that, where a proposed rule authorizes or requires use of commercial standards, the notice of proposed rulemaking must inform the public of the use and background of such standards. In addition, section 32(c) requires DOE to consult with the Attorney General and the Chairman of the Federal Trade Commission (FTC) concerning the impact of the commercial or industry standards on competition.

Today's final rule incorporates testing methods contained in the following commercial standards: ANSI Standard C82.2–1984, "American National Standard for Fluorescent Lamp Ballasts—Method of Measurement, 1984," and ANSI Standard C82.2–2002, "American National Standard for Lamp Ballasts—Method of Measurement of Fluorescent Lamp Ballasts, 2002." The Department has evaluated these standards and is unable to conclude whether they fully comply with the requirements of section 32(b) of the FEAA, (i.e., that they were developed in a manner that fully provides for public participation, comment, and review). 74 FR 3450, 3459 (Jan. 21, 2009). DOE has consulted with the Attorney General and the Chairman of the FTC

concerning the impact on competition of requiring manufacturers to use the test methods contained in these standards, and neither recommended against incorporation of these standards.

M. Congressional Notification

As required by 5 U.S.C. 801, DOE will report to Congress on the promulgation of today's rule before its effective date. The report will state that it has been determined that the rule is not a "major rule" as defined by 5 U.S.C. 801(2).

V. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this final rule.

List of Subjects in 10 CFR Part 430

Administrative practice and procedure, Confidential business information, Energy conservation, Household appliances, Imports, Incorporation by reference, Intergovernmental relations, Small businesses.

Issued in Washington, DC, on September 17, 2009.

Cathy Zoi,

Assistant Secretary, Energy Efficiency and Renewable Energy.

■ For the reasons stated in the preamble, part 430 of Chapter II of Title 10, Code of Federal Regulations, is amended as set forth below:

PART 430—ENERGY CONSERVATION PROGRAM FOR CONSUMER PRODUCTS

■ 1. The authority citation for part 430 continues to read as follows:

Authority: 42 U.S.C. 6291–6309; 28 U.S.C. 2461 note.

■ 2. Section 430.3 is amended by:

■ a. Redesignating paragraph (c)(12) as (c)(13);

■ b. Adding a new paragraph (c)(12);

■ c. Redesignating paragraphs (d), (e), (f), (g), (h), (i), (j), (k), (l), (m), and (n) as (e), (f), (g), (h), (i), (j), (k), (l), (m), (n), and (o) respectively; and

■ d. Adding a new paragraph (d).

The additions read as follows:

§ 430.3 Materials incorporated by reference.

* * * * *

(c) * * *

(12) ANSI Standard C82.2–2002, Revision of ANSI C82.2–1994 (R1995), American National Standard for Lamp Ballasts—Method of Measurement of Fluorescent Lamp Ballasts, approved June 6, 2002, IBR approved for Appendix Q to Subpart B.

* * * * *

(d) *ANSI Reseller.* Global Engineering Documents, 15 Inverness Way, East Englewood, CO 80112, Phone: 800.854.7179 or 303.397.7956, <http://www.global.ihs.com>, E-mail: global@ihs.com. DOE does not endorse any particular reseller and notes that other resellers may also have the superseded standard for sale. Consult <http://webstore.ansi.org/> for more information on additional resellers.

(1) ANSI C82.2–1984, Revision of ANSI C82.2–1977, American National Standard for Fluorescent Lamp Ballasts—Method of Measurement, approved October 21, 1983, IBR approved for Appendix Q to Subpart B.

(2) [Reserved].

* * * * *

■ 3. Section 430.23 is amended by redesignating paragraph (q)(4) as paragraph (q)(5) and adding a new paragraph (q)(4) to read as follows:

§ 430.23 Test procedures for the measurement of energy and water consumption.

* * * * *

(q) *Fluorescent Lamp Ballasts.* * * *

(4) Standby power consumption of certain fluorescent lamp ballasts shall be measured in accordance with section 3.5 of appendix Q to Subpart B of Part 430.

* * * * *

■ 4. Appendix Q to Subpart B of Part 430 is amended by:

■ a. Redesignating paragraphs 1.12 through 1.16 as paragraphs 1.15 through 1.19; paragraphs 1.3 through 1.11 as paragraphs 1.5 through 1.13; and paragraphs 1.1 and 1.2 as paragraphs 1.2 and 1.3, respectively.

■ b. Removing from redesignated paragraphs 1.5 through 1.10, and redesignated paragraphs 1.15 through 1.17, and paragraphs 3.2, 3.31, 3.3.2, 3.3.3, 3.4.1 and 3.4.2, "S(s)tandard" after the word "ANSI" and adding "(incorporated by reference; see § 430.3)" before the period at the end of each paragraph.

■ c. Adding new paragraphs 1.1, 1.4, 1.14, 1.20 and 3.5

■ d. Revising redesignated paragraph 1.19 and paragraphs 2 and 3.1.

These revisions and additions read as follows:

Appendix Q to Subpart B of Part 430—Uniform Test Method for Measuring the Energy Consumption of Fluorescent Lamp Ballasts

1. Definitions

1.1 *AC control signal* means an alternating current (AC) signal that is supplied to the ballast using additional wiring for the purpose of controlling the

ballast and putting the ballast in standby mode.

* * * * *

1.4 *DC control signal* means a direct current (DC) signal that is supplied to the ballast using additional wiring for the purpose of controlling the ballast and putting the ballast in standby mode.

* * * * *

1.14 *PLC control signal* means a power line carrier (PLC) signal that is supplied to the ballast using the input ballast wiring for the purpose of controlling the ballast and putting the ballast in standby mode.

* * * * *

1.19 *Standby mode* means the condition in which an energy-using product—

(a) Is connected to a main power source; and

(b) Offers one or more of the following user-oriented or protective functions:

(i) To facilitate the activation or deactivation of other functions (including active mode) by remote switch (including remote control), internal sensor, or timer.

(ii) Continuous functions, including information or status displays (including clocks) or sensor-based functions.

1.20 *Wireless control signal* means a wireless signal that is radiated to and received by the ballast for the purpose of controlling the ballast and putting the ballast in standby mode.

2. Test Conditions

2.1 *Measurement of Electric Supply and Light Output.* The test conditions for testing fluorescent lamp ballasts shall be done in accordance with the ANSI C82.2–1984, (incorporated by reference; see § 430.3). Any subsequent amendment to this standard by the standard-setting organization will not affect the DOE test procedures unless and until amended by DOE. The test conditions are described in sections 4, 5, 6, 7, and 21 of ANSI C82.2–1984. The test conditions described in this section (2.1) are applicable to sections 3.3 and 3.4 of section 3, Test Method and Measurements.

2.2 *Measurement of Standby Mode Power.* The measurement of standby mode power need not be performed to determine compliance with energy conservation standards for fluorescent lamp ballasts at this time. The above statement will be removed as part of the rulemaking to amend the energy conservation standards for fluorescent lamp ballasts to account for standby mode energy consumption, and the following shall apply on the compliance date for such requirements.

The test conditions for testing fluorescent lamp ballasts shall be done in accordance with the American National Standard Institute ANSI C82.2–2002 (incorporated by reference; see § 430.3). Any subsequent amendment to this standard by the standard-setting organization will not affect the DOE test procedures unless and until amended by DOE. The test conditions for measuring standby power are described in sections 5, 7, and 8 of ANSI C82.2–2002. The test conditions described in this section (2.2) are applicable to section 3.5 of 3, Test Method and Measurements. Fluorescent lamp ballasts

that are capable of connections to control devices shall be tested with all commercially available compatible control devices connected in all possible configurations. For each configuration, a separate measurement of standby power shall be made in accordance with section 3.5 of the test procedure.

3. Test Method and Measurements

3.1 The test method for testing fluorescent lamp ballasts shall be done in accordance with ANSI C82.2-1984 (incorporated by reference; see § 430.3). The

test for measuring standby mode energy consumption of fluorescent lamp ballasts shall be done in accordance with ANSI C82.2-2002 (incorporated by reference; see § 430.3).

* * * * *

3.5 Standby Mode Power Measurement

3.5.1 Send a signal to the ballast instructing it to have zero light output using the appropriate ballast communication protocol or system for the ballast being tested.

3.5.2 *Input Power.* Measure the input power (watts) to the ballast in accordance with ANSI C82.2-2002, section 13, (incorporated by reference; see § 430.3).

3.5.3 *Control Signal Power.* The power from the control signal path will be measured using all applicable methods described below.

3.5.3.1 *AC Control Signal.* Measure the AC control signal power (watts), using a wattmeter (W), connected to the ballast in accordance with the circuit shown in Figure 1.

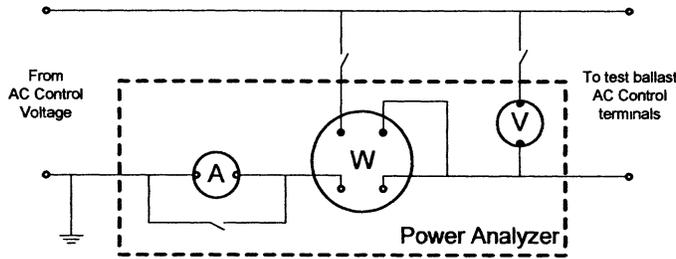


Figure 1: Circuit for Measuring AC Control Signal Power in Standby Mode

3.5.3.2 *DC Control Signal.* Measure the DC control signal voltage, using a voltmeter (V), and current, using an ammeter (A),

connected to the ballast in accordance with the circuit shown in Figure 2. The DC control signal power is calculated by multiplying the

DC control signal voltage and the DC control signal current.

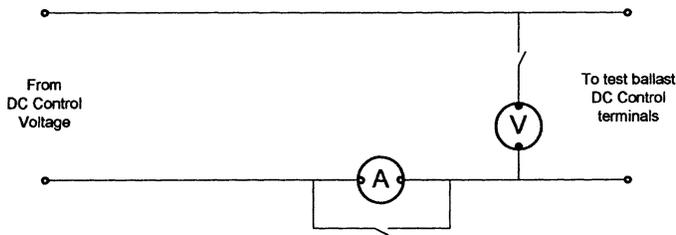


Figure 2: Circuit for Measuring DC Control Signal Power in Standby Mode

3.5.3.3 *Power Line Carrier (PLC) Control Signal.* Measure the PLC control signal power (watts), using a wattmeter (W), connected to the ballast in accordance with the circuit

shown in Figure 3. The wattmeter must have a frequency response that is at least 10 times higher than the PLC being measured in order to measure the PLC signal correctly. The

wattmeter must also be high-pass filtered to filter out power at 60 Hertz.

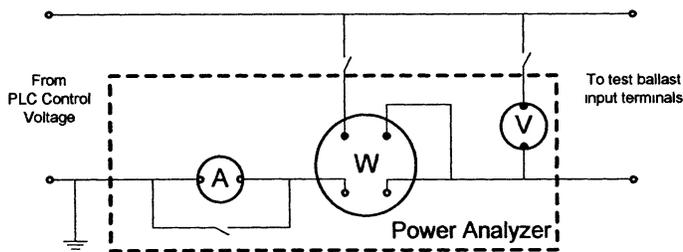


Figure 3: Circuit for Measuring PLC Control Signal Power in Standby Mode

3.5.3.4 *Wireless Control Signal.* The power supplied to a ballast using a wireless signal is not easily measured, but is estimated to be well below 1.0 watt. Therefore, the wireless control signal power is not measured as part of this test procedure.

[FR Doc. E9-25325 Filed 10-21-09; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. NM408; Special Conditions No. 25-391-SC]

Special Conditions: Alenia Model C-27J Airplane; Liquid Oxygen System

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions.

SUMMARY: These special conditions are issued for the Alenia Model C-27J airplane. This airplane will have novel or unusual design features when compared to the state of technology described in the airworthiness standards for transport-category airplanes. These design features include a liquid-oxygen (LOX) system. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for oxygen systems that use liquid oxygen. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: *Effective Date:* November 23, 2009.

FOR FURTHER INFORMATION CONTACT: Tom Groves, FAA, International Branch, ANM-116, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue, SW., Renton, Washington 98057-3356; telephone (425) 227-1503, facsimile (425) 227-1149.

SUPPLEMENTARY INFORMATION:

Background

On March 27, 2006, the European Aviation Safety Agency (EASA) forwarded to the FAA an application from Alenia Aeronautica of Torino, Italy, for U.S. type certification of a twin-engine commercial transport designated as the Model C-27J. The C-27J is a twin-turbopropeller, cargo-transport aircraft with a maximum takeoff weight of 30,500 kilograms.

Type Certification Basis

Under the provisions of section 21.17 of Title 14, Code of Federal Regulations (14 CFR) and the bilateral agreement between the U.S. and Italy, Alenia Aeronautica must show that the C-27J meets the applicable provisions of 14 CFR part 25, as amended by Amendments 25-1 through 25-87. Alenia also elects to comply with Amendment 25-122, effective September 5, 2007, for 14 CFR 25.1317.

If the Administrator finds that existing airworthiness regulations do not adequately or appropriately address safety standards for the C-27J due to a novel or unusual design feature, the FAA prescribes special conditions under provisions of 14 CFR 21.16.

In addition to the applicable airworthiness regulations and special conditions, the C-27J must comply with the fuel-vent and exhaust-emission requirements of 14 CFR part 34 and the noise-certification requirements of 14 CFR part 36, and the FAA must issue a finding of regulatory adequacy pursuant to § 611 of Public Law 92-574, the "Noise Control Act of 1972."

The FAA issues special conditions, as defined in 14 CFR 11.19, in accordance with § 11.38, and they become part of the type-certification basis under § 21.17(a)(2).

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same or similar novel or unusual design feature, the special conditions also apply to the other model under § 21.101.

Novel or Unusual Design Features

The Alenia Model C-27J incorporates a liquid-oxygen system, including a liquid-oxygen converter, valves, evaporating coils, lines, regulators, indicators, fittings, etc. The existing airworthiness regulations do not adequately or appropriately address safety standards for the design and installation of oxygen systems that utilize liquid oxygen. These special conditions for the C-27J contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards for these novel or unusual design features.

Discussion

There are no specific regulations that address the design and installation of oxygen systems that utilize liquid oxygen for storage. Existing

requirements, such as §§ 25.1309, 25.1441(b) and (c), 25.1451, and 25.1453, in the Alenia C-27J certification basis, provide some design standards for crew and medical-oxygen-system installations. However, additional design standards for oxygen systems utilizing liquid oxygen are needed to supplement the existing applicable requirements. The quantity of liquid oxygen involved in this installation and the potential for hazards that may result when the oxygen content of an enclosed area becomes too high because of system leaks, malfunction, or damage from external sources, make it necessary to assure adequate safety standards are applied to the design and installation of the system in Alenia C-27J airplanes. These special conditions require Alenia to preclude or minimize the risk of these potential hazards. These special conditions are also intended to assure the safe operation of the liquid-oxygen system, and therefore require that:

- Adequate gaseous oxygen is available at temperatures appropriate for breathing;
- The liquid-oxygen converter and gaseous-oxygen-distribution lines are installed in locations that minimize their potential for damage;
- The quantity of available oxygen is clearly indicated to the flight crew;
- The system is designed to prevent leakage of oxygen into the cabin;
- Condensation from the system is collected and drained overboard;
- The system must be protected from possible ignition sources and structural damage; and
- Appropriate maintenance and operational instructions are provided to ensure the system's safe operation.

Taken together, these requirements would ensure that this liquid-oxygen system provides an equivalent level of safety to traditional oxygen systems.

Discussion of Comments

Notice of proposed special conditions no. 25-09-04-SC for the Alenia model C-27J airplane was published in the **Federal Register** on July 13, 2009. No comments were received, and the special conditions are adopted as proposed.

Applicability

As discussed above, these special conditions are applicable to the Alenia C-27J. Should Alenia apply at a later date for a change to the type certificate to include another airplane model incorporating the same novel or unusual design features, these special conditions apply to that model as well under § 21.101.

Conclusion

This action affects only certain novel or unusual design features of the Alenia C-27J. It is not a rule of general applicability, and it affects only the applicant that applied to the FAA for approval of these features on the airplane.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

■ The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701, 44702, 44704.

The Special Conditions

■ Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for the C-27J airplane.

General

1. The liquid-oxygen system must be located to minimize the possibility of exposure of occupants to liquid oxygen from a leak or condensation.

2. The liquid-oxygen converter must be located in the airplane so that there is no risk of damage to the converter due to an uncontained rotor or propeller-blade failure.

3. The liquid-oxygen system's associated gaseous-oxygen-distribution lines should be designed and located to minimize the hazard from uncontained rotor or propeller-blade debris.

4. The flight-deck oxygen system must meet the supply requirements of part 121 in the event the oxygen-distribution line is severed by a rotor or propeller-blade fragment.

5. The pressure-relief valves on the liquid-oxygen converters must be vented overboard. The ventilation means must be configured such that liquid and gaseous oxygen will be exhausted so that oxygen will not accumulate inside the airplane. Means must be provided to prevent hydrocarbon-fluid migration from impinging upon the vent outlet of the liquid-oxygen system.

6. The system must include provisions to ensure complete conversion of the liquid oxygen to gaseous oxygen. The resultant oxygen gas must be delivered to the first oxygen outlet for breathing such that the temperature is no more than 35°F less than the cabin ambient temperature or 32°F (whichever is greater), under the conditions of the maximum demand or flow of oxygen gas for normal use of the oxygen system. A liquid-oxygen shutoff valve must be installed on the main

oxygen-distribution line prior to any secondary lines. The shutoff valve must be both compatible with liquid-oxygen temperatures and readily accessible (either directly if manual, or by remote activation if automatic).

7. If multiple converters are used, the design should ensure that a leak in one converter does not result in leakage of oxygen from any other converter.

8. Approved flexible hoses must be used for the airplane-systems connections to shock-mounted converters, where movement relative to the airplane may occur.

9. Condensation from system components or lines must be collected by drip pans, shields, or other suitable collection means, and drained overboard through a drain fitting separate from the liquid-oxygen vent fitting, as specified in special condition 5, above.

10. Oxygen-system components must be burst-pressure tested to 3.0 times, and proof-pressure tested to 1.5 times, the maximum normal operating pressure. Compliance with the requirement for burst testing may be shown by similarity analysis, or a combination of similarity analysis and test.

11. Oxygen-system components must be electrically bonded to the airplane structure.

12. All gaseous or liquid-oxygen connections located in close proximity to an ignition source must be shrouded and vented overboard using the system specified in special condition 5, above.

13. A means must be provided to indicate to the flight crew the quantity of available oxygen.

14. Instructions for Continued Airworthiness (ICA) per § 25.1529 must be provided for the safe operation and maintenance of the liquid-oxygen system.

15. Emergency procedures must be developed for the aircraft crew to address aircraft-safety-related malfunctions of the liquid-oxygen system.

16. The liquid-oxygen-system equipment, including the tank, must be retained under all loads up to those specified in § 25.561(b)(3). The tank must be able to resist rupture and to retain the liquid oxygen, under the inertia forces prescribed for the emergency-landing conditions in § 25.561. In addition, the tank must be able to withstand, without failure, the vibration, inertia, fluid, and structural loads that it may be subjected to in operation. The liquid-oxygen components, including the tank, must

be protected from scraping or impact from baggage, cargo, or other contents.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E9-25396 Filed 10-21-09; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

14 CFR Part 97

[Docket No. 30691; Amdt. No. 3343]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective October 22, 2009. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of October 22, 2009.

ADDRESSES: Availability of matter incorporated by reference in the amendment is as follows:

For Examination

1. FAA Rules Docket, FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591;

2. The FAA Regional Office of the region in which the affected airport is located;

3. The National Flight Procedures Office, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or

4. 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.

Availability—All SIAPs are available online free of charge. Visit nfdc.faa.gov to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from:

1. FAA Public Inquiry Center (APA-200), FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591; or

2. The FAA Regional Office of the region in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT:

Harry J. Hodges, Flight Procedure Standards Branch (AFS-420) Flight Technologies and Programs Division, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 (Mail Address: P.O. Box 25082 Oklahoma City, OK 73125) telephone: (405) 954-4164.

SUPPLEMENTARY INFORMATION: This rule amends Title 14, Code of Federal Regulations, Part 97 (14 CFR part 97) by amending the referenced SIAPs. The complete regulatory description of each SIAP is listed on the appropriate FAA Form 8260, as modified by the National Flight Data Center (FDC)/Permanent Notice to Airmen (P-NOTAM), and is incorporated by reference in the amendment under 5 U.S.C. 552(a), 1 CFR part 51, and § 97.20 of Title 14 of the Code of Federal Regulations.

The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and

publication of the complete description of each SIAP contained in FAA form documents is unnecessary. This amendment provides the affected CFR sections and specifies the types of SIAP and the corresponding effective dates. This amendment also identifies the airport and its location, the procedure and the amendment number.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP as amended in the transmittal. For safety and timeliness of change considerations, this amendment incorporates only specific changes contained for each SIAP as modified by FDC/P-NOTAMs.

The SIAPs, as modified by FDC P-NOTAM, and contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these changes to SIAPs, the TERPS criteria were applied only to specific conditions existing at the affected airports. All SIAP amendments in this rule have been previously issued by the FAA in a FDC NOTAM as an emergency action of immediate flight safety relating directly to published aeronautical charts. The circumstances which created the need for all these SIAP amendments requires making them effective in less than 30 days.

Because of the close and immediate relationship between these SIAPs and safety in air commerce, I find that notice and public procedure before adopting these SIAPs are impracticable and contrary to the public interest and, where applicable, that good cause exists for making these SIAPs effective in less than 30 days.

Conclusion

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a “significant regulatory action” under Executive Order 12866; (2) is not a

“significant rule” under DOT regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Incorporation by reference, and Navigation (Air).

Issued in Washington, DC, on October 2, 2009.

John M. Allen,

Director, Flight Standards Service.

Adoption of the Amendment

■ Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal Regulations, Part 97, 14 CFR part 97, is amended by amending Standard Instrument Approach Procedures, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721-44722.

■ 2. Part 97 is amended to read as follows:

§§ 97.23, 97.25, 97.27, 97.29, 97.31, 97.33, and 97.35 [Amended]

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, Identified as follows:

* * * *Effective Upon Publication*

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
19-Nov-09	DE	MIDDLETOWN	SUMMIT	9/0193	9/16/09	NDB-A, AMDT 7.
19-Nov-09	PA	POTTSTOWN	POTTSTOWN LIMERICK	9/0454	9/17/09	GPS RWY 28, ORIG.
19-Nov-09	PA	POTTSTOWN	POTTSTOWN LIMERICK	9/0455	9/17/09	GPS RWY 10, ORIG.
19-Nov-09	PA	POTTSTOWN	POTTSTOWN LIMERICK	9/0456	9/17/09	TAKEOFF MINS AND OBSTACLE DP, AMDT 2.
19-Nov-09	PA	POTTSTOWN	POTTSTOWN LIMERICK	9/0458	9/17/09	VOR/DME-A, AMDT 3A.
19-Nov-09	PA	POTTSTOWN	POTTSTOWN LIMERICK	9/0459	9/17/09	LOC RWY 28, AMDT 2A.
19-Nov-09	NY	SARATOGA SPRINGS ...	SARATOGA COUNTY	9/0596	9/18/09	RNAV (GPS) RWY 5, AMDT 1.
19-Nov-09	NY	SARATOGA SPRINGS ...	SARATOGA COUNTY	9/0597	9/18/09	VOR/DME-A, AMDT 1.
19-Nov-09	MD	CRISFIELD	CRISFIELD MUNI	9/0937	9/21/09	VOR/DME-A, ORIG.

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
19–Nov–09	NC	ELIZABETH CITY	ELIZABETH CITY CG AIR STATION/RGNL.	9/0944	9/21/09	NDB RWY 10, ORIG–D.
19–Nov–09	NC	ELIZABETH CITY	ELIZABETH CITY CG AIR STATION/RGNL.	9/0945	9/21/09	VOR/DME RWY 19, AMDT 10C.
19–Nov–09	NJ	NEWARK	NEWARK LIBERTY INTL	9/1291	9/22/09	VOR RWY 11, AMDT 2A.
19–Nov–09	MD	STEVENSVILLE	BAY BRIDGE	9/1416	9/23/09	RNAV (GPS) RWY 11, ORIG.
19–Nov–09	NC	REIDSVILLE	ROCKINGHAM COUNTY NC SHILOH.	9/1640	9/24/09	VOR/DME A, AMDT 9.
19–Nov–09	VT	RUTLAND	SOUTHERN VERMONT RGNL.	9/1642	9/24/09	VOR/DME RWY 1, AMDT 1.
19–Nov–09	VT	RUTLAND	SOUTHERN VERMONT RGNL.	9/1658	9/24/09	RNAV (GPS) RWY 1, ORIG.
19–Nov–09	OK	OKLAHOMA CITY	WILL ROGERS WORLD	9/2522	9/29/09	ILS OR LOC/DME RWY 35L, ORIG–A.
19–Nov–09	OH	CLEVELAND	CLEVELAND-HOPKINS INTL.	9/2530	9/29/09	ILS PRM RWY 24R (SIM. CLOSE PARALLEL), ORIG.
19–Nov–09	OH	CLEVELAND	CLEVELAND-HOPKINS INTL.	9/2531	9/29/09	LDA PRM RWY 24L (SIM. CLOSE PARALLEL), ORIG.
19–Nov–09	OH	CLEVELAND	CLEVELAND-HOPKINS INTL.	9/2533	9/29/09	LDA PRM RWY 6R (SIM. CLOSE PARALLEL), AMDT 1.
19–Nov–09	OH	CLEVELAND	CLEVELAND-HOPKINS INTL.	9/2534	9/29/09	ILS PRM RWY 6L (SIM. CLOSE PARALLEL), ORIG–A.
17–Dec–09	MI	DETROIT	DETROIT METROPOLITAN WAYNE COUNTY.	9/0505	9/17/09	ILS OR LOC Z RWY 22R, AMDT 2.
17–Dec–09	MI	DETROIT	DETROIT METROPOLITAN WAYNE COUNTY.	9/0506	9/17/09	ILS PRM RWY 22R (SIM. CLOSE PARALLEL), ORIG.
17–Dec–09	MI	DETROIT	DETROIT METROPOLITAN WAYNE COUNTY.	9/0507	9/17/09	ILS OR LOC Z RWY 4L, AMDT 3.
17–Dec–09	MI	DETROIT	DETROIT METROPOLITAN WAYNE COUNTY.	9/0508	9/17/09	ILS PRM RWY 4L (SIM. CLOSE PARALLEL), ORIG.
17–Dec–09	NC	ANDREWS	ANDREWS-MURPHY	9/1638	9/24/09	RNAV (GPS) RWY 8, ORIG.
17–Dec–09	TX	HOUSTON	DAVID WAYNE HOOKS MEMORIAL.	9/1783	9/24/09	LOC RWY 17R, AMDT 1.

[FR Doc. E9–24328 Filed 10–21–09; 8:45 am]
 BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 30690; Amdt. No 3342]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are

designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective October 22, 2009. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of October 22, 2009.

ADDRESSES: Availability of matters incorporated by reference in the amendment is as follows:

For Examination

1. FAA Rules Docket, FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591;
2. The FAA Regional Office of the region in which the affected airport is located;
3. The National Flight Procedures Office, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,
4. 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.

Availability—All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit <http://www.nfdc.faa.gov> to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from:

1. FAA Public Inquiry Center (APA–200), FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591; or
2. The FAA Regional Office of the region in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT:

Harry J. Hodges, Flight Procedure Standards Branch (AFS–420), Flight Technologies and Programs Divisions, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd. Oklahoma City, OK. 73169 (Mail Address: P.O. Box 25082, Oklahoma City, OK 73125) Telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This rule amends Title 14 of the Code of Federal Regulations, Part 97 (14 CFR part 97), by

establishing, amending, suspending, or revoking SIAPs, Takeoff Minimums and/or ODPS. The complete regulators description of each SIAP and its associated Takeoff Minimums or ODP for an identified airport is listed on FAA form documents which are incorporated by reference in this amendment under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR part 97.20. The applicable FAA Forms are FAA Forms 8260-3, 8260-4, 8260-5, 8260-15A, and 8260-15B when required by an entry on 8260-15A.

The large number of SIAPs, Takeoff Minimums and ODPS, in addition to their complex nature and the need for a special format make publication in the **Federal Register** expensive and impractical. Furthermore, airmen do not use the regulatory text of the SIAPs, Takeoff Minimums or ODPS, but instead refer to their depiction on charts printed by publishers of aeronautical materials. The advantages of incorporation by reference are realized and publication of the complete description of each SIAP, Takeoff Minimums and ODP listed on FAA forms is unnecessary. This amendment provides the affected CFR sections and specifies the types of SIAPs and the effective dates of the associated Takeoff Minimums and ODPS. This amendment also identifies the airport and its location, the procedure, and the amendment number.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP, Takeoff Minimums and ODP as contained in the transmittal. Some SIAP and Takeoff Minimums and textual ODP amendments may have been issued previously by the FAA in a Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flight safety relating directly to published aeronautical charts. The circumstances which created the need for some SIAP and Takeoff Minimums and ODP amendments may require making them effective in less than 30 days. For the remaining SIAPs and Takeoff Minimums and ODPS, an effective date at least 30 days after publication is provided.

Further, the SIAPs and Takeoff Minimums and ODPS contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these SIAPs and Takeoff Minimums and ODPS, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and

ODPs, and safety in air commerce, I find that notice and public procedures before adopting these SIAPs, Takeoff Minimums and ODPS are impracticable and contrary to the public interest and, where applicable, that good cause exists for making some SIAPs effective in less than 30 days.

Conclusion

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) Is not a “significant regulatory action” under Executive Order 12866; (2) is not a “significant rule” under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Incorporation by reference, and Navigation (Air).

Issued in Washington, DC, on October 2, 2009.

John M. Allen,

Director, Flight Standards Service.

Adoption of the Amendment

■ Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal Regulations, Part 97 (14 CFR part 97) is amended by establishing, amending, suspending, or revoking Standard Instrument Approach Procedures and/or Takeoff Minimums and/or Obstacle Departure Procedures effective at 0902 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721-44722.

■ 2. Part 97 is amended to read as follows:

Effective 19 Nov 2009

Davis Woodland, CA, Yolo County, RNAV (GPS) RWY 16, Orig-A

Davis Woodland, CA, Yolo County, RNAV (GPS) RWY 34, Orig-A

Fernandina Beach, FL, Fernandina Beach Muni, Takeoff Minimums and Obstacle DP, Orig

New Smyrna Beach, FL, Massey Ranch Airpark, Takeoff Minimums and Obstacle DP, Orig

Monroe, GA, Monroe-Walton County, NDB-A, Amdt 1

Monroe, GA, Monroe-Walton County, RNAV (GPS) RWY 3, Amdt 1

Harrisburg, PA, Harrisburg Intl, Takeoff Minimums and Obstacle DP, Amdt 8

Columbia, SC, Jim Hamilton L.B. Owens, Takeoff Minimums and Obstacle DP, Amdt 3

Fayetteville, TN, Fayetteville Muni, NDB RWY 20, Amdt 5

Platteville, WI, Platteville Muni, NDB RWY 25, Amdt 5, CANCELLED

Effective 17 Dec 2009

Barter Island, AK, Barter Island LRRS, Takeoff Minimums and Obstacle DP, Orig Deadhorse, AK, Deadhorse, RNAV (GPS) RWY 5, Amdt 1A

Deadhorse, AK, Deadhorse, RNAV (GPS) RWY 23, Amdt 1A

Fairbanks, AK, Fairbanks Intl, RNAV (GPS) X RWY 1L, Orig, CANCELLED

Fairbanks, AK, Fairbanks Intl, RNAV (GPS) X RWY 19R, Orig, CANCELLED

Holy Cross, AK, Holy Cross, RNAV (GPS) RWY 1, Orig-A

Holy Cross, AK, Holy Cross, RNAV (GPS) RWY 19, Orig-A

Kipnuk, AK, Kipnuk, Takeoff Minimums and Obstacle DP, Orig

Kotzebue, AK, Ralph Wien Memorial, ILS OR LOC/DME RWY 9, Amdt 2

Point Hope, AK, Point Hope, Takeoff Minimums and Obstacle DP, Orig

Unalakleet, AK, Unalakleet, LOC/DME RWY 15, Amdt 3A

Unalakleet, AK, Unalakleet, VOR/DME-D, Amdt 4A

Wainwright, AK, Wainwright, NDB RWY 5, Amdt 1

Wainwright, AK, Wainwright, NDB RWY 23, Amdt 1

Wainwright, AK, Wainwright, RNAV (GPS) RWY 5, Amdt 1

Wainwright, AK, Wainwright, RNAV (GPS) RWY 23, Amdt 1

Wainwright, AK, Wainwright, Takeoff Minimums and Obstacle DP, Orig

Chico, CA, Chico Muni, ILS OR LOC/DME RWY 13L, Amdt 12

Livermore, CA, Livermore Muni, GPS RWY 25R, Orig-B, CANCELLED

Livermore, CA, Livermore Muni, RNAV (GPS) RWY 25R, Orig

Los Banos, CA, Los Banos Muni, RNAV (GPS) RWY 14, Orig

Los Banos, CA, Los Banos Muni, RNAV (GPS) RWY 32, Orig

Los Banos, CA, Los Banos Muni, Takeoff Minimums and Obstacle DP, Amdt 2

Los Banos, CA, Los Banos Muni, VOR/DME RWY 14, Amdt 5

Los Banos, CA, Los Banos Muni, VOR/DME RWY 32, Amdt 5

Tampa, FL, Tampa Intl, ILS OR LOC RWY 18R, Amdt 4B

Tampa, FL, Tampa Intl, RNAV (GPS) RWY 18R, Amdt 1A

Boise, ID, Boise Air Terminal/Gowen Fld, ILS OR LOC/DME RWY 28R, Orig, CANCELLED

Pocatella, ID, Pocatello Regional, Takeoff Minimums and Obstacle DP, Amdt 7

Mattoon/Charleston, IL, Coles County Memorial, ILS OR LOC RWY 29, Amdt 6

Mattoon/Charleston, IL, Coles County Memorial, NDB RWY 29, Amdt 5

Mattoon/Charleston, IL, Coles County Memorial, RNAV (GPS) RWY 24, Orig

Mattoon/Charleston, IL, Coles County Memorial, Takeoff Minimums and Obstacle DP, Amdt 4

Mattoon/Charleston, IL, Coles County Memorial, VOR RWY 6, Amdt 13

Mattoon/Charleston, IL, Coles County Memorial, VOR RWY 24, Amdt 11

Anderson, IN, Anderson Muni-Darlington Field, ILS OR LOC RWY 30, Amdt 1

Anderson, IN, Anderson Muni-Darlington Field, NDB RWY 30, Amdt 6

Anderson, IN, Anderson Muni-Darlington Field, RNAV (GPS) RWY 30, Orig

Anderson, IN, Anderson Muni-Darlington Field, VOR-A, Amdt 9

Tompkinsville, KY, Tompkinsville-Monroe County, RNAV (GPS) RWY 4, Orig

Tompkinsville, KY, Tompkinsville-Monroe County, RNAV (GPS) RWY 22, Orig

Tompkinsville, KY, Tompkinsville-Monroe County, Takeoff Minimums and Obstacle DP, Orig

Winnefield, LA, David G. Joyce, GPS RWY 26, Orig-A, CANCELLED

Winnefield, LA, David G. Joyce, RNAV (GPS) RWY 9, Orig

Winnefield, LA, David G. Joyce, RNAV (GPS) RWY 27, Orig

Winnefield, LA, David G. Joyce, Takeoff Minimums and Obstacle DP, Orig

Fremont, MI, Fremont Muni, Takeoff Minimums and Obstacle DP, Orig

Fremont, MI, Fremont Muni, VOR RWY 18, Orig-A

Fremont, MI, Fremont Muni, VOR RWY 36, Amdt 7A

Pontiac, MI, Oakland County Intl, RNAV (GPS) RWY 27L, Orig

Sturgis, MI, Kirsch Muni, RNAV (GPS) RWY 36, Orig

Dickinson, ND, Dickinson-Theodore Roosevelt Rgnl, RNAV (GPS) RWY 32, Amdt 2

David City, NE, David City Muni, RNAV (GPS) RWY 14, Amdt 1

David City, NE, David City Muni, RNAV (GPS) RWY 32, Amdt 1

David City, NE, David City Muni, Takeoff Minimums and Obstacle DP, Amdt 1

David City, NE, David City Muni, VOR/DME RWY 32, Amdt 1

Norfolk, NE, Karl Stefan Memorial, RNAV (GPS) RWY 1, Amdt 1A

Norfolk, NE, Karl Stefan Memorial, RNAV (GPS) RWY 14, Amdt 1

Norfolk, NE, Karl Stefan Memorial, RNAV (GPS) RWY 19, Amdt 1B

Norfolk, NE, Karl Stefan Memorial, RNAV (GPS) RWY 32, Amdt 1

Norfolk, NE, Karl Stefan Memorial, Takeoff Minimums and Obstacle DP, Orig

Wooster, OH, Wayne County, GPS RWY 28, Amdt 1A, CANCELLED

Wooster, OH, Wayne County, RNAV (GPS) RWY 10, Orig

Wooster, OH, Wayne County, RNAV (GPS) RWY 28, Orig

Wooster, OH, Wayne County, VOR RWY 10, Amdt 1

Guthrie, OK, Guthrie-Edmond Rgnl, Takeoff Minimums and Obstacle DP, Amdt 1

Hamilton, TX, Hamilton Muni, GPS RWY 36, Orig-A, CANCELLED

Hamilton, TX, Hamilton Muni, NDB RWY 36, Amdt 1

Hamilton, TX, Hamilton Muni, RNAV (GPS) RWY 18, Orig

Hamilton, TX, Hamilton Muni, RNAV (GPS) RWY 36, Orig

Hamilton, TX, Hamilton Muni, Takeoff Minimums and Obstacle DP, Orig

Seattle, WA, Boeing Field/King County Intl, ILS RWY 13R, Amdt 29

Seattle, WA, Boeing Field/King County Intl, LOC/DME RWY 13R, Amdt 2

Elkins, WV, Elkins-Randolph Co-Jennings RA, GPS RWY 5, Orig-A, CANCELLED

Elkins, WV, Elkins-Randolph Co-Jennings RA, GPS RWY 23, Orig-B, CANCELLED

Elkins, WV, Elkins-Randolph Co-Jennings RA, RNAV (GPS)-A, Orig

Elkins, WV, Elkins-Randolph Co-Jennings RA, RNAV (GPS) RWY 5, Orig

Elkins, WV, Elkins-Randolph Co-Jennings RA, RNAV (GPS) RWY 14, Orig

Elkins, WV, Elkins-Randolph Co-Jennings RA, RNAV (GPS) RWY 23, Orig

Spencer, WV, Boggs Field, RNAV (GPS) RWY 10, Orig

Spencer, WV, Boggs Field, RNAV (GPS) RWY 28, Orig

Spencer, WV, Boggs Field, Takeoff Minimums and Obstacle DP, Orig

[FR Doc. E9-24347 Filed 10-21-09; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 35

[Docket No. RM09-24-000; Order No. 727]

Interest Rates for Refunds

Issued October 15, 2009.

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Final rule.

SUMMARY: The Commission is revising its regulations governing the interest rates used in calculating refunds. Because the Federal Reserve no longer publishes Statistical Release G. 13, which was previously referenced in the Commission's regulations, and Statistical Release G. 13 has been superseded by Statistical Release H. 15, this Final Rule revises the Commission's regulations to now reference the Federal Reserve's Statistical Release H. 15.

DATES: *Effective Date:* This rule is effective October 22, 2009.

FOR FURTHER INFORMATION CONTACT:

Rachel Spiker (Technical Information), Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, (202) 502-8801, rachel.spiker@ferc.gov.

Moon Athwal (Legal Information), Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, (202) 502-6272, moon.athwal@ferc.gov.

SUPPLEMENTARY INFORMATION:

Before Commissioners: Jon Wellingshoff, Chairman; Sudeen G. Kelly, Marc Spitzer, and Philip D. Moeller.

I. Discussion

1. The Commission is revising its regulations governing the interest rates used in calculating refunds to reflect a change in the Federal Reserve's publications. Currently, the regulations reference the Federal Reserve's Statistical Release G. 13 for the calculation of the average prime rate for each calendar quarter used in determining refunds.¹ The Federal Reserve no longer publishes Statistical Release G. 13, and Statistical Release G. 13 has been superseded by Statistical Release H. 15.² Accordingly, this Final Rule revises the Commission's regulations to now refer to the Federal Reserve's Statistical Release H. 15. The methods for calculating refunds or for determining the applicable interest rates are not being altered in any way.

II. Information Collection Statement

2. The Office of Management and Budget's (OMB) regulations require that OMB approve certain information collection requirements imposed by agency rule.³ This Final Rule does not contain information collection requirements and is not subject to OMB approval.

III. Environmental Analysis

3. The Commission is required to prepare an Environmental Assessment or an Environmental Impact Statement for any action that may have a significant adverse effect on the quality of the human environment.⁴ Issuance of this Final Rule does not represent a major federal action having a significant adverse effect on the quality of the human environment under the Commission's regulations implementing the National Environmental Policy Act of 1969. Part 380 of the Commission's regulations lists exemptions to the requirement to draft an Environmental Analysis or Environmental Impact Statement. Included is an exemption for

¹ 18 CFR 35.19a(a)(2)(iii)(A)(2009).

² Federal Reserve, *Discontinuance of the G.13* (Sept. 4, 2001), <http://www.federalreserve.gov/releases/g13/g13note.htm>.

³ 5 CFR part 1320.

⁴ *Regulations Implementing the National Environmental Policy Act*, Order No. 486, 52 FR 47897 (Dec. 17, 1987), FERC Stats. & Regs. ¶ 30,783 (1987).

procedural, ministerial or internal administrative actions and management.⁵ This rulemaking is exempt under that provision.

IV. Regulatory Flexibility Act

4. The Regulatory Flexibility Act of 1980 (RFA)⁶ generally requires a description and analysis of final rules that will have significant economic impact on a substantial number of small entities. This final rule makes a ministerial correction to the regulations, correcting the reference to a Federal Reserve Statistical Release. The Commission certifies that it will not have a significant economic impact on a substantial number of small entities. An analysis under the RFA is not required.

V. Document Availability

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

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

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

VI. Effective Date

8. These regulations are effective October 22, 2009. In accordance with 5 U.S.C. 553(d)(3), the Commission finds that good cause exists to make this Final Rule effective immediately. It corrects an out-of-date reference in the Commission's regulations to reflect a change in the Federal Reserve's Statistical Releases. It will not

significantly and adversely affect persons appearing before the Commission. There is therefore no reason to make this rule effective at a later time.

9. The Commission is issuing this rule as a Final Rule without a period for public comment. Under 5 U.S.C. 553(b), notice and comment procedures are unnecessary where a rulemaking concerns only agency procedure and practice, or where the agency finds that notice and comment are unnecessary.⁷ The Commission finds that notice and comment are unnecessary because the Commission is merely correcting a reference to a no longer published Federal Reserve Statistical Release. No new burden or regulatory requirement is imposed on regulated entities or the general public. Instead, this Final Rule merely updates an out-of-date reference in the Commission's regulations to reflect a change in the Federal Reserve's Statistical Releases.

List of Subjects in 18 CFR Part 35

Electric power rates, Electric utilities, Reporting requirements.

By the Commission.

Kimberly D. Bose,
Secretary.

■ In consideration of the foregoing, the Commission amends part 35, Chapter I, Title 18, *Code of Federal Regulations*, as follows:

PART 35—FILING OF RATE SCHEDULES AND TARIFFS

■ 1. The authority citation for part 35 continues to read as follows:

Authority: 16 U.S.C. 791a–825r, 2601–2645; 31 U.S.C. 9701; 42 U.S.C. 7101–7352.

§ 35.19 [Amended]

■ 2. In § 35.19a, paragraph (a)(2)(iii)(A) is amended to remove the phrase “Statistical Release G. 13” and to add the phrase “Statistical Release H. 15” in its place.

[FR Doc. E9–25253 Filed 10–21–09; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 358

[Docket No. RM07–1–001; Order No. 717–A]

Standards of Conduct for Transmission Providers

Issued October 15, 2009.

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Final rule; order on rehearing and clarification.

SUMMARY: The Federal Energy Regulatory Commission (Commission) generally reaffirms its determinations in Order No. 717, but grants rehearing on and clarifies certain provisions. Order No. 717–A aims to make the Standards of Conduct clearer and to refocus the rules on the areas where there is the greatest potential for abuse. The order addresses requests for rehearing and clarification of the following issues: Applicability of the Standards of Conduct to transmission owners with no marketing affiliate transactions; whether the Independent Functioning Rule applies to balancing authority employees; which activities of transmission function employees or marketing function employees are subject to the Independent Functioning Rule; whether local distribution companies making off-system sales on nonaffiliated pipelines are subject to the Standards of Conduct; whether the Standards of Conduct apply to a pipeline's sale of its own production; applicability of the Standards of Conduct to asset management agreements; whether incidental purchases to remain in balance or sales of unneeded gas supply subject the company to the Standards of Conduct; applicability of the No Conduit Rule to certain situations; and applicability of the Transparency Rule to certain situations.

DATES: *Effective Date:* This rule will become effective November 23, 2009.

FOR FURTHER INFORMATION CONTACT: Leonard Tao, Office of the General Counsel—Energy Markets, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, (202) 502–8214.

SUPPLEMENTARY INFORMATION:

Federal Reserve Statistical Release, and otherwise does not change the methods for calculating refunds or for determining the applicable interest rates. *See* 5 U.S.C. 804(3)(C).

⁵ 18 CFR 380.4(1).

⁶ 5 U.S.C. 601–12.

⁷ We similarly find that this rule does not substantially affect the rights or obligations of parties to Commission proceedings, since it merely corrects a reference to a no longer published

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Before Commissioners: Jon Wellinghoff, Chairman; Sueden G. Kelly, Marc Spitzer, and Philip D. Moeller.

I. Introduction

1. On October 16, 2008, the Commission issued Order No. 717 amending the Standards of Conduct for Transmission Providers (the Standards of Conduct or the Standards) to make them clearer and to refocus the rules on the areas where there is the greatest potential for abuse.¹ In this order, the Commission addresses requests for rehearing and clarification of Order No. 717.

II. Background

2. The Commission first adopted the Standards of Conduct in 1988, in Order No. 497.² The Commission adopted similar Standards for the electric

industry in 1996, in Order No. 889,³ prohibiting public utilities from giving undue preferences to their marketing affiliates or wholesale merchant functions. Both the electric and gas Standards sought to deter undue preferences by (i) separating a transmission provider’s employees engaged in transmission services from those engaged in its marketing services, and (ii) requiring that all transmission customers, affiliated and non-affiliated, be treated on a non-discriminatory basis.

3. In 2003, the Commission issued Order No. 2004,⁴ which broadened the

Standards to include a new category of affiliate, the energy affiliate.⁵ The new Standards were made applicable to both the electric and gas industries, and provided that the transmission employees of a transmission provider⁶ must function independently not only from the company’s marketing affiliates but from its energy affiliates as well, and that transmission providers may not treat either their energy affiliates or their marketing affiliates on a preferential basis. Order No. 2004 also imposed requirements to publicly post information concerning a transmission provider’s energy affiliates. On appeal, the U.S. Court of Appeals for the D.C.

¹ *Standards of Conduct for Transmission Providers*, Order No. 717, 73 FR 63796 (Oct. 27, 2008), FERC Stats. & Regs. ¶ 31,280 (2008) (Order No. 717).

² *Inquiry Into Alleged Anticompetitive Practices Related to Marketing Affiliates of Interstate Pipelines*, Order No. 497, 53 FR 22139 (Jun. 14, 1988), FERC Stats. & Regs., Regulations Preambles 1986–1990 ¶ 30,820 (1988); Order No. 497–A, *order on rehearing*, 54 FR 52781 (Dec. 22, 1989), FERC Stats. & Regs., Regulations Preambles 1986–1990 ¶ 30,868 (1989); Order No. 497–B, *order extending sunset date*, 55 FR 53291 (Dec. 28, 1990), FERC Stats. & Regs., Regulations Preambles 1986–1990 ¶ 30,908 (1990); Order No. 497–C, *order extending sunset date*, 57 FR 9 (Jan. 2, 1992), FERC Stats. & Regs., Regulations Preambles 1991–June 1996 ¶ 30,934 (1991), *rehearing denied*, 57 FR 5815 (Feb. 18, 1992), 58 FERC ¶ 61,139 (1992); *aff’d in part and remanded in part sub nom. Tenneco Gas v. FERC*, 969 F.2d 1187 (D.C. Cir. 1992) (Tenneco) (collectively, Order No. 497).

³ *Open Access Same-Time Information System (Formerly Real-Time Information Network) and Standards of Conduct*, Order No. 889, 61 FR 21737 (May 10, 1996), FERC Stats. & Regs., Regulations Preambles January 1991–June 1996 ¶ 31,035 (1996); Order No. 889–A, *order on reh’g*, 62 FR 12484 (Mar. 14, 1997), FERC Stats. & Regs., Regulations Preambles July 1996–December 2000 ¶ 31,049 (1997); Order No. 889–B, *reh’g denied*, 62 FR 64715 (Dec. 9, 1997), 81 FERC ¶ 61,253 (1997) (collectively, Order No. 889).

⁴ *Standards of Conduct for Transmission Providers*, Order No. 2004, FERC Stats. & Regs. ¶ 31,155 (2003), *order on rehearing*, Order No. 2004–A, FERC Stats. & Regs. ¶ 31,161, *order on rehearing*, Order No. 2004–B, FERC Stats. & Regs. ¶ 31,166, *order on rehearing*, Order No. 2004–C, FERC Stats. & Regs. ¶ 31,172 (2004), *order on rehearing*, Order No. 2004–D, 110 FERC ¶ 61,320 (2005), *vacated and remanded as it applies to natural gas pipelines sub nom. National Fuel Gas Supply Corp. v. FERC*, 468 F.3d 831 (D.C. Cir. 2006) (*National Fuel*); *see Standards of Conduct for Transmission Providers*, Order No. 690, FERC Stats. & Regs. ¶ 31,237, *order on rehearing*, Order No. 690–A, FERC Stats. & Regs. ¶ 31,243 (2007); *see also Standards of Conduct for Transmission Providers*, Notice of Proposed Rulemaking, FERC

Stats. & Regs. ¶ 32,611 (2007); Notice of Proposed Rulemaking, FERC Stats. & Regs. ¶ 32,630 (2008).

⁵ The Order 2004 standards of conduct defined an energy affiliate as an affiliate of a transmission provider that (1) engages in or is involved in transmission transactions in U.S. energy or transmission markets; (2) manages or controls transmission capacity of a transmission provider in U.S. energy or transmission markets; (3) buys, sells, trades or administers natural gas or electric energy in U.S. energy or transmission markets; or (4) engages in financial transactions relating to the sale or transmission of natural gas or electric energy in U.S. energy or transmission markets. Order No. 2004, FERC Stats. & Regs. ¶ 31,155 at P 40; *see also* 18 CFR 358.3(d). Certain categories of entities were excluded from this definition in subsequent subsections of the regulations.

⁶ A transmission provider was defined as (1) any public utility that owns, operates or controls facilities used for transmission of electric energy in interstate commerce; or (2) any interstate natural gas pipeline that transports gas for others pursuant to subpart A of part 157 or subparts B or G of part 284 of the same chapter of the regulations. Order No. 2004, FERC Stats. & Regs. ¶ 31,155 at P 33–34; *see also* 18 CFR 358.3(a).

Circuit overturned the Standards as applied to gas transmission providers, on the grounds that the evidence of energy affiliate abuse cited by the Commission was not in the record.⁷

4. The Commission issued an Interim Rule on January 9, 2007,⁸ which repromulgated the portions of the Standards not challenged in *National Fuel* as applied to natural gas transmission providers. On January 18, 2007, the Commission issued its initial notice of proposed rulemaking (NOPR),⁹ requesting comment on a variety of issues, including whether the concept of energy affiliates should be retained for the electric industry. Following consideration of the comments filed and the Commission's own experience in administering the Standards, the Commission modified the approach advanced in the initial NOPR. The Commission issued a second NOPR on March 21, 2008,¹⁰ and invited comment both on its general approach and on its specific provisions. In the second NOPR, the Commission proposed to return to the approach of separating by function transmission personnel from marketing personnel, an approach that had been adopted in Order Nos. 497 and 889. The Commission also proposed to clarify and streamline the Standards in order to enhance compliance and enforcement, and to increase transparency in the area of transmission/affiliate interactions to aid in the detection of any undue discrimination.

5. The reforms adopted in Order No. 717 were intended to eliminate the elements that have rendered the Standards difficult to enforce and apply. They combined the best elements of Order No. 2004 (especially the integration of gas and electric Standards, an element not contested in *National Fuel*) with those of the Standards originally adopted for the gas industry in Order No. 497 and for the electric industry in Order No. 889. Specifically, Order No. 717 (i) eliminated the concept of energy affiliates and (ii) eliminated the corporate separation approach in favor of the employee functional approach

used in Order Nos. 497 and 889. In addition, the reforms adopted in Order No. 717 conformed the Standards with the *National Fuel* opinion.

III. Discussion

A. Jurisdiction and Applicability of the Standards: Applicability to Transmission Providers With No Marketing Affiliate Transactions

6. In Order No. 717, we addressed the question of whether the Standards' applicability to interstate pipelines in § 358.1(a) should parallel the Standards' applicability to the electric industry in § 358.1(b). Section 358.1(a) generally states that part 358 applies to any interstate pipeline that transports gas for others and conducts transmission transactions with an affiliate that engages in marketing functions.¹¹ In contrast, the NOPR proposed that § 358.1(b) should state only that this part applies to any public utility that owns, operates, or controls facilities used for the transmission of electric energy in interstate commerce. The specific question addressed in Order No. 717 concerned the phrase "and conducts transmission transactions with an affiliate that engages in marketing functions" and whether this language should be retained in § 358.1(a).¹²

7. We determined that the language in § 358.1(a) should parallel the language in § 358.1(b) since there was no evidence in the record that pipelines that do not conduct transmission transactions with an affiliate engaged in marketing functions are in a position to engage in the type of affiliate abuse to which the Standards are directed.¹³ We concluded that rather than remove the phrase in question from § 358.1(a), this provision should be added to § 358.1(b) so that the limitation would apply to public utilities as well as pipelines.¹⁴ We found that a public utility or a pipeline that does not engage in any transmission transactions with a marketing affiliate should be excluded from the Standards coverage.

Requests for Rehearing and Clarification

8. Several parties raise the issue of the applicability of the Standards to marketing function employees of affiliates that do not conduct transmission transactions with affiliated transmission providers. For example, the Electric Power Supply Association (EPSA) interprets these provisions as applying the Standards only to

transmission companies that conduct transactions with their marketing affiliates. According to EPSA, some pipeline/transmission providers have multiple marketing affiliates and these providers do not engage in transactions with all of their affiliates.¹⁵ EPSA states that it is unclear whether that pipeline or transmission provider is subject to the Standards with all of its marketing affiliates, or just those with which it conducts transactions.¹⁶ EPSA argues that the Independent Functioning Rule in § 358.5 should only apply to the relationship between the transmission function employees and the marketing function employees of those marketing affiliates with which the provider conducts transactions.¹⁷

9. The Interstate Natural Gas Association of America (INGAA), MidAmerican Energy Holdings Company (MidAmerican), and the Edison Electric Institute (EEI) also interpret the Standards as not extending to employees of affiliates that do not conduct transmission transactions with the pipeline or public utility transmission provider.¹⁸ INGAA states that it is unclear how the regulations apply where a pipeline has at least one affiliate engaged in marketing functions that conducts transmission transactions on the pipeline, but has other affiliates that do not. INGAA argues that the Standards cannot lawfully be applied to marketing function employees of affiliates that do not conduct transmission transactions with the affiliated pipeline.¹⁹ INGAA contends that if the Standards are intended to apply to the relationship between a pipeline and the marketing function employees of affiliates that do not conduct transmission transactions on that affiliated pipeline, the Commission has exceeded its authority.²⁰

10. MidAmerican argues that when an affiliate does not engage in transmission transactions on an affiliated transmission provider's system, there is little or no potential for affiliate abuse, and to the extent that there could be inappropriate interaction with affiliates, such conduct is already proscribed by the No Conduit Rule in § 358.6 and the Transparency Rule in § 358.7.²¹

⁷ *National Fuel*, 468 F.3d at 841.

⁸ *Standards of Conduct for Transmission Providers*, Order No. 690, 72 FR 2427 (Jan. 19, 2007); FERC Stats. & Regs. ¶ 31,237 (2007) (Interim Rule); *clarified by, Standards of Conduct for Transmission Providers*, Order No. 690-A, 72 FR 14235 (Mar. 27, 2007); FERC Stats. & Regs. ¶ 31,243 (2007).

⁹ *Standards of Conduct for Transmission Providers*, 72 FR 3958 (Jan. 29, 2007), FERC Stats. & Regs. ¶ 32,611 (2007).

¹⁰ *Standards of Conduct for Transmission Providers*, 73 FR 16228 (Mar. 27, 2008), FERC Stats. & Regs. ¶ 32,630 (2008).

¹¹ 18 CFR 358.1(a) (2009).

¹² Order No. 717, FERC Stats. & Regs. ¶ 31,280 at P 16.

¹³ *Id.* P 20.

¹⁴ *Id.* P 23.

¹⁵ EPSA Nov. 17, 2008 Request for Clarification at 2.

¹⁶ *Id.* at 3.

¹⁷ *Id.* at 4.

¹⁸ INGAA Nov. 17, 2008 Request for Clarification and Rehearing at 4; MidAmerican Nov. 17, 2008 Request for Rehearing or Clarification at 5; EEI Nov. 17, 2008 Request for Clarification at 12–13.

¹⁹ INGAA at 7–9.

²⁰ *Id.*

²¹ MidAmerican at 5.

11. MidAmerican is concerned that paragraph 104 of Order No. 717 suggests that all marketing function employees within a corporate holding company structure are to be considered marketing function employees of all affiliated transmission providers.²² MidAmerican contends that employees of an affiliate who engage in marketing functions are not likely to be privy to non-public transmission function information of an affiliated transmission provider unless the affiliate engages in transmission transactions with that transmission provider.²³ MidAmerican further argues that to the extent that an employee of an affiliate engaged in marketing functions became privy to non-public transmission function information about another affiliated transmission provider's system, he or she is still proscribed from being a conduit for that information under the Standards and the transmission provider would also have the obligation to post the disclosed information pursuant to the Transparency Rule.²⁴

12. EEI requests clarification that, regardless of whether a corporate family owns electric transmission providers, gas transmission providers, or both, that the Standards of Conduct apply only (a) between transmission function employees of a gas transmission provider and employees within the corporate family engaged in gas marketing functions, and (b) between transmission function employees of an electric transmission provider and employees within the corporate family engaged in electric marketing functions.²⁵ EEI contends that it would be unfair to subject companies with both gas and electric transmission providers to restrictions on relationships that do not apply to the same relationships in companies that have only gas or only electric transmission providers.²⁶

13. EEI states that paragraphs 16–23 of Order No. 717 indicate that the rules only apply between transmission function employees and those marketing function employees who are employed by a company that conducts transmission transactions with the transmission provider. EEI requests clarification as to whether this interpretation is accurate.²⁷

14. Under EEI's interpretation of these provisions, an employee that makes sales of electric energy is performing a

marketing function only if that employee works for a public utility transmission provider or a company that is affiliated with such a provider.²⁸ EEI requests confirmation of this interpretation.

15. The Transmission Access Policy Study Group (TAPS) argues that the Commission should either eliminate the exemption for electric transmission providers that do not conduct transmission transactions with marketing affiliates, or clarify that transmission owners in regional transmission organizations (RTOs) remain subject to the Standards absent a waiver.²⁹ TAPS contends that if this exemption is not eliminated for the electric transmission providers, transmission owners in RTO regions may interpret § 358.1(b) as exempting them from the Standards regardless of whether they have sought and obtained a waiver.³⁰ Specifically, TAPS argues that the Commission should expand upon “conduct transmission transactions with an affiliate that engages in marketing functions.”³¹ According to TAPS, transmission owners within an RTO may argue that only the RTO conducts transmission transactions with market participants and thus these transmission owners would be exempt from the Standards.³² Alternatively, TAPS asks that the Commission clarify that the new language in § 358.1(b) does not exempt transmission owners in RTO regions who conduct marketing activities (or who have affiliates that are engaged in marketing activities) in the RTO market.³³

Commission Determination

16. Consistent with our findings in Order No. 717 that a public utility or interstate natural gas pipeline that does not engage in any transmission transactions with a marketing affiliate should be excluded from the Standards' coverage,³⁴ we clarify that the term “marketing function employee” of a transmission provider, as defined in § 358.3(d), does not include an employee of an affiliate that does not engage in transmission transactions on the affiliated transmission provider's transmission system. Furthermore, we note that § 358.1(a) and (b) generally limit the applicability of the Standards

of Conduct to transmission providers that conduct transmission transactions with an affiliate that engages in marketing functions.

17. In response to EEI, we confirm that an employee who makes sales of electric energy is performing a marketing function only if the employee works for a public utility transmission provider or a company affiliated with such a provider.

18. We deny TAPS' request that we eliminate the exemption for electric transmission providers that do not conduct transmission transactions with marketing affiliates. As described above, the Commission determined in Order No. 717 that “a public utility that does not engage in any transmission transactions with a marketing affiliate should be excluded from the Standards' coverage”³⁵ because there is no evidence that this type of relationship triggers concerns that the public utility will engage in undue preference in favor of an affiliate. However, we clarify that a public utility transmission owner that is in a Commission-approved RTO or that is part of a Commission-approved independent system operator (ISO) and has access to non-public transmission function information remains subject to the Standards of Conduct unless it has obtained a waiver.

B. Independent Functioning Rule

19. In Order No. 717, we continued the policy of requiring transmission function employees of a transmission provider to function independently of the marketing function employees of the transmission provider. This policy is referred to as the Independent Functioning Rule. The relevant consideration for purposes of applying the Independent Functioning Rule is the function performed by the employee himself. To implement this approach, we defined several key terms, including “transmission functions” (§ 358.3(h)), “marketing functions” (§ 358.3(c)), and “transmission function employees” (§ 358.3(i)).

20. We defined “transmission functions” as “the planning, directing, organizing or carrying out of day-to-day transmission operations, including the granting and denying of transmission service requests.”³⁶ Through this definition, we intended to focus on “those areas most susceptible to affiliate abuse,” which we identified as “short-term real time operations, including those decisions made in advance of real

²² *Id.* at 7.

²³ *Id.* at 7–11.

²⁴ *Id.* at 8.

²⁵ EEI at 12.

²⁶ *Id.*

²⁷ *Id.* at 13.

²⁸ *Id.* at 11–12.

²⁹ TAPS Nov. 17, 2008 Petition for Rehearing or Clarification at 29.

³⁰ *Id.* at 30.

³¹ *Id.* at 31.

³² *Id.*

³³ *Id.* at 33.

³⁴ Order No. 717, FERC Stats. & Regs. ¶ 31,280 at P 20 and P 23.

³⁵ *Id.* P 23.

³⁶ *Id.* P 40.

time but directed at real time operations.”³⁷

21. With regard to the definition of transmission function employee, we agreed that field, maintenance and construction workers, as well as engineers and clerical workers, are not normally involved in the day-to-day operations of the transmission system. Thus, in general they would not fall within the scope of the definition of transmission function employee.³⁸ However, we declined to add a further exclusion in the definition for *de minimis* involvement.³⁹ We also found that the question of whether balancing authority personnel are included in the definition of transmission function employee depends on the circumstances. If the transmission provider also serves as a balancing authority and an employee’s duties encompass both transmission provider and balancing authority activities, the employee is a transmission function employee.⁴⁰ We also provided several examples of what activities constitute the day-to-day operation of the transmission system. Included in these examples was balancing load with energy or capacity.⁴¹

1. Transmission Function

22. Both Wisconsin Electric Power Company (Wisconsin Electric) and EEI request further clarification of whether personnel that balance load with energy or capacity are considered “transmission function employees” under the Standards.⁴² EEI contends that economic decisions regarding the source of energy or capacity to be used to balance load may be made by marketing function employees and requests that the Commission affirmatively find that such activities are not transmission functions.⁴³ Wisconsin Electric argues that the Commission’s statement in paragraph 122 of Order No. 717 that balancing load with energy or capacity is among the day-to-day operations of the transmission system is inconsistent with the Commission’s statement in paragraph 48 of Order No. 717 that excluded a balancing authority from the definition of a “transmission function employee” where the balancing authority and transmission functions are separate, and the employee performs no duties outside of

those specific to a balancing authority employee.⁴⁴

23. Wisconsin Electric requests that the Commission clarify that a balancing area employee who balances load with generation (including scheduled interchange) and performs no other transmission functions is not a “transmission function employee” for purposes of the Standards.⁴⁵ If the Commission intends that balancing load with energy or capacity is a transmission function, then Wisconsin Electric requests that the Commission clarify and identify which of the other balancing authority requirements under the NERC Reliability Standards are also transmission functions and which are not.⁴⁶

Commission Determination

24. We clarify that paragraph 122 of Order No. 717 incorrectly included “balancing load with energy or capacity” as an example of what is included in the day-to-day operation of the transmission system. As we stated in Order No. 717, “[i]f the transmission provider also serves as a balancing authority, and an employee’s duties encompass both transmission provider and balancing authority activities, such an employee would be a transmission function employee (provided his or her duties are encompassed by the definition of transmission function employee). If, however, the two functions are separate, and the employee performs no duties outside of those specific to a balancing authority employee, he or she would not be considered a transmission function employee.”⁴⁷ Thus, personnel who balance load with energy or generating capacity are not considered “transmission function employee[s]” under the Standards where the balancing authority and transmission functions are separate, and the employee does not perform duties or tasks of a transmission function employee.⁴⁸

2. Transmission Function Employees

25. TAPS is concerned that the transmission function definition places too much emphasis on short-term or real-time operations in an effort to exclude long-term planning employees

from the transmission function and that this emphasis might be misconstrued.⁴⁹ Specifically, TAPS is concerned that the short-term focus might be misinterpreted as limiting the Commission’s determination that employees engaged in the “granting and denying of transmission service requests” are transmission function employees.⁵⁰ TAPS asks the Commission to clarify that personnel engaged in “granting or denying transmission service requests” are transmission function employees regardless of the duration of service requested.⁵¹

26. TAPS also asks the Commission to clarify that the transmission function includes not just the employees who post on the OASIS that a particular request has been granted or denied but, also, the employees who are responsible for performing the underlying system impact studies or otherwise determining whether the transmission system can support the requested services.⁵² TAPS asserts that engineers who make engineering decisions regarding the operation and maintenance of transmission facilities and engineers who determine whether transmission requests can be accommodated by the existing transmission system are clearly performing activities that are integral to a transmission provider’s administration of its tariff and are central to the “planning, directing, organizing or carrying out of day-to-day transmission operations, including the granting and denying of transmission service requests.”⁵³

Commission Determination

27. The Commission clarifies that personnel engaged in “granting or denying transmission service requests” are transmission function employees regardless of the duration of service requested. We find that granting or denying of transmission service requests is an integral part of “planning, directing, organizing or carrying out of day-to-day transmission operations.”⁵⁴ The Commission also clarifies that “transmission function employee” includes an employee responsible for performing system impact studies or determining whether the transmission system can support the requested services as this type of employee is planning, directing, organizing or

⁴⁴ Wisconsin Electric at 4.

⁴⁵ *Id.*

⁴⁶ *Id.* at 5.

⁴⁷ Order No. 717 at P 48.

⁴⁸ We reiterate that the No Conduit Rule still applies and would prohibit the transmission provider from using personnel who balance load with energy or generating capacity as conduits for the disclosure of non-public transmission information to marketing function employees.

⁴⁹ TAPS at 41.

⁵⁰ *Id.*

⁵¹ *Id.*

⁵² *Id.* at 42–43.

⁵³ *Id.* at 42–43 (citing 18 CFR 358.3(h)).

⁵⁴ 18 CFR 258.3(h).

³⁷ *Id.*

³⁸ *Id.* P 46.

³⁹ *Id.* P 47.

⁴⁰ *Id.* P 48.

⁴¹ *Id.* P 122.

⁴² Wisconsin Electric Nov. 17, 2008 Request for Clarification at 3; EEI at 7.

⁴³ EEI at 7.

carrying out the day-to-day transmission operations.

3. Marketing Functions

28. In Order No. 717, we made the Standards applicable to “any public utility that owns, operates, or controls facilities used for the transmission of electric energy in interstate commerce and conducts transmission transactions with an affiliate that engages in marketing functions”⁵⁵ and also any interstate natural gas pipeline that transports gas for others and “conducts transmission transactions with an affiliate that engages in marketing functions.”⁵⁶

29. As noted above, we defined several terms in the order. Marketing functions include “in the case of public utilities and their affiliates, the sale for resale in interstate commerce, or the submission of offers to sell in interstate commerce, of * * * financial or physical transmission rights.”⁵⁷ We adopted the following definition of marketing functions for pipelines and their affiliates: “The sale for resale in interstate commerce, or the submission of offers to sell in interstate commerce, natural gas, subject to the following exclusions: (i) Bundled retail sales, (ii) Incidental purchases or sales of natural gas to operate interstate natural gas pipeline transmission facilities, (iii) Sales of natural gas solely from a seller’s own production, (iv) Sales of natural gas solely from a seller’s own gathering or processing facilities, and (v) Sales by an intrastate natural gas pipeline, by a Hinshaw pipeline exempt from the Natural Gas Act (NGA), or by a local distribution company making an on-system sale.”⁵⁸ We also defined a marketing function employee as “an employee, contractor, consultant or agent of a transmission provider or of an affiliate of a transmission provider who actively and personally engages on a day-to-day basis in marketing functions.”

a. Electric Industry

30. EEI seeks clarification as to which sales of transmission rights are marketing functions, and which sales are transmission functions.⁵⁹ EEI suggests that as a general rule, any sale of transmission service under an open access transmission service or a pre-Order No. 888 grandfathered agreement be considered a transmission function, while any resale or reassignment of such

service should be considered a marketing function.⁶⁰ EEI also suggests that the rule must allow the limited sorts of “resale” that occur from a facility that has been leased, or when transmission is being provided on a back-to-back basis, to be treated as transmission functions, not marketing functions.⁶¹

31. TAPS requests that the Commission restore (1) the Order 889-era separation of transmission function employees from employees engaged in purchases for wholesale sales;⁶² and (2) Order 2004’s required separation of transmission function personnel from employees making purchases for retail load.⁶³ TAPS also contends that the Commission should require the separation of transmission function personnel from employees making bundled retail sales.⁶⁴ TAPS argues that the marketing definition should be revised to include bids to buy products traded in organized markets, particularly financial transmission rights.⁶⁵ Finally, TAPS requests reconsideration of the Commission’s decision to exempt from the marketing definition retail sales by a provider of last resort (POLR).⁶⁶

32. Transmission Dependent Utility Systems (TDUS) asks that the Commission exclude from the definition of marketing functions sales by generation and transmission cooperatives to their members.⁶⁷ According to TDUS, Order No. 717 eliminated purchasing-related activities from coverage under the Standards.⁶⁸ TDUS states that under the new Standards, employees of generation and transmission cooperatives will not be subject to the Standards due to their purchasing activities alone.⁶⁹ However, TDUS believes that there is a question left as to whether such employees’ involvement in sales of power to members will subject them to the Standards and asserts that it should not.⁷⁰ TDUS asserts that because the generation and transmission cooperative’s role with respect to its member load is nearly identical to that of a vertically integrated investor-owned utility’s role with respect to its retail load, employees of generation and

transmission cooperatives should have the same access to generation and transmission function information as the employees of investor-owned utilities.⁷¹

Commission Determination

33. We grant EEI’s request for clarification that any sale of transmission service under an open access transmission service or a pre-Order No. 888 grandfathered agreement be considered a transmission function, while any resale or reassignment of such service be considered a marketing function. Under Order No. 890, a transmission customer may sell all or a portion of its transmission rights to an eligible customer (*i.e.*, an assignee). When this type of transaction occurs, the transmission customer becomes a reseller and the assignee must sign a service agreement with the transmission provider. The transmission provider is obligated to credit or charge the reseller for any difference in price between the assignee’s agreement and the reseller’s original agreement.⁷² Thus, the transmission provider continues in the role of providing transmission service and makes the payments to both the reseller and its customer. However, the resale or reassignment between the reseller and the assignee is a marketing function.

34. While we grant EEI’s requested clarification as discussed above, we reject its suggestion that limited sorts of “resale” that occur from a facility being leased, or transmission that is provided on a back-to-back basis, be treated as transmission functions. We deny this clarification because EEI has failed to adequately support or explain its request. We note, however, that EEI appears to be describing a narrow set of circumstances that may be more suitable for a waiver request.

35. We deny TAPS’ request for rehearing that the marketing function definition be amended to include purchases as well as sales. As we noted in Order No. 717, restricting the definition of marketing function to include only sales more closely matches the statutory prohibitions against undue preference.⁷³ Specifically, sections 205 and 206 of the Federal Power Act prohibit undue preference or advantage

⁶⁰ *Id.*

⁶¹ *Id.*

⁶² TAPS at 13–22.

⁶³ *Id.* at 22–26.

⁶⁴ *Id.* at 26–29.

⁶⁵ *Id.* at 33–36.

⁶⁶ *Id.* at 37–40.

⁶⁷ TDUS Nov. 17, 2008 Request for Clarification or Rehearing at 2–3.

⁶⁸ *Id.* at 2.

⁶⁹ *Id.*

⁷⁰ *Id.*

⁷¹ *Id.* at 3.

⁷² *Preventing Undue Discrimination and Preference in Transmission Service*, Order No. 890, FERC Stats. & Regs. ¶ 31,241, *order on rehearing*, Order No. 890–A, FERC Stats. & Regs. ¶ 31,261 (2007), *order on rehearing*, Order No. 890–B, 123 FERC ¶ 61,299 (2008) *order on rehearing*, Order No. 890–C, 126 FERC ¶ 61,228 (2009).

⁷³ Order No. 717, FERC Stats. & Regs. ¶ 31,280 at P 77.

⁵⁵ 18 CFR 358.1(b).

⁵⁶ 18 CFR 358.1(a).

⁵⁷ 18 CFR 358.3(c)(1).

⁵⁸ Order No. 717, FERC Stats. & Regs. ¶ 31,280 at P 83.

⁵⁹ EEI at 14–15.

to any person with respect to “any transmission or sale subject to the jurisdiction of the Commission * * *.”⁷⁴ Similarly, sections 4 and 5 of the Natural Gas Act prohibit undue preference with respect to “any transportation or sale of natural gas subject to the jurisdiction of the Commission * * *.”⁷⁵ Because the Commission’s authority to impose the Standards of Conduct to prevent undue preference is rooted in these sections, we find that TAPS’ request to expand the marketing function definition to include purchases to be inconsistent with our statutory authority.

36. In response to the TAPS statement that excluding employees responsible for purchases from the reach of the Standards of Conduct alters the Commission’s approach in Order No. 889, we note that in Order No. 717 the Commission found that the removal of purchases from the definition of marketing function “frees companies to conduct the informational exchanges necessary to engage in integrated resource planning, and eliminates the difficulties which might otherwise be experienced by executive personnel who have overall procurement responsibilities that include both transmission and marketing. At the same time, it preserves the protection against affiliate abuse, as it is those employees who are making wholesale sales of electricity, not purchases, who can improperly benefit from transmission function information obtained from the affiliated transmission provider.”⁷⁶ Given these findings and the Commission’s consideration of its more than decade-long experience implementing the Order No. 889 provisions, we reiterate that there is no need to include purchases in the marketing function definition as a means of preventing undue preference.⁷⁷ For these same reasons, we also deny TAPS’ request that we require the separation of transmission function employees from those employees making purchases for retail load and its request that we include bids to buy

products within the definition of marketing function.

37. Similarly, we reject TAPS’ request that employees making bundled retail sales⁷⁸ be included in the definition of marketing function. In Order No. 888, the Commission stated that it had exclusive jurisdiction over the rates, terms and conditions of unbundled retail transmission in interstate commerce.⁷⁹ However, the Commission declined to assert jurisdiction over bundled retail transmission, reasoning that “when transmission is sold at retail as part and parcel of the delivered product called electric energy, the transaction is a sale of electric energy at retail.”⁸⁰ The U.S. Supreme Court affirmed the Commission’s decision to assert jurisdiction over unbundled but not bundled retail transmission, finding that the Commission made a statutorily permissible choice.⁸¹ TAPS essentially is asking us to end this long-standing jurisdictional divide, at least with regard to the Standards. We decline to do so.

38. We also deny TAPS’ request that we reconsider the decision to exempt retail sales by a POLR from the definition of marketing functions. TAPS asserts that POLR service constitutes unbundled retail sales.⁸² However, the Commission stated in Order No. 2004 that POLR sales could be accorded treatment equivalent to that accorded to bundled retail sales.⁸³ Bundled retail sales are sales where the power and transmission components associated with the sale of electric energy to retail customers are provided together in a single bundled package.⁸⁴ The

important distinction between unbundled and retail sales is that the generation component may be purchased separately in unbundled service.⁸⁵ Under POLR service the generation offered can only be purchased through the regulated public utility as a part of the “bundled” package of transmission, distribution and generation. Generally, POLR service is offered in states that permit retail competition. POLR service is also generally state-mandated with either state-approved rates or a part of a state-approved and regulated process for deriving the generation price. The POLR service is provided to retail customers on a default basis and POLR employees do not market POLR service.

39. Previously, we declined to accord POLR service the same exemption as other bundled retail sales, opting instead to consider its status on a case-by-case basis.⁸⁶ The Commission has granted past waivers based on the fact that POLR employees do not market POLR service, do not engage in competitive functions and do not schedule or reserve transmission service.⁸⁷ This experience with waiver requests has led us to the conclusion that no justification exists for treating POLR sales differently than other bundled retail sales. Therefore, we will deny TAPS’ request for rehearing concerning POLR.

40. Finally, as TDUS requests, we clarify that if an employee of a generation and transmission cooperative simply serves retail load and does not engage in activities included in the “marketing functions” definition in § 358.3, then this employee is not a “marketing function employee.”

electric energy and the cost of its delivery. *New York v. FERC*, 535 U.S. 1, 5 (2002).

⁸⁵ We note that even if the rates or prices for components are separately stated, or itemized, on the end users’ bills this does not render the POLR service “unbundled.” See, e.g., *Northern Natural Gas Co., v. FERC*, 929 F.2d 1261, 1273 (8th Cir. 1991). (Stating a rate separately from the related jurisdictional rate does not “magically unbundle” the activity).

⁸⁶ TAPS’ reliance on the few cases in which we denied a waiver request is misplaced. None of the denials were based on the risk of abuse being too great. For example, in *Allegheny Power Service Corp.*, 85 FERC ¶ 61,390 (1998), Allegheny requested a waiver of the functional unbundling requirement with regard to employees who made wholesale purchases for unbundled retail sales. Thus, this decision does not constitute precedent regarding a request for a bundled retail sales waiver. See also, *PECO*, 89 FERC ¶ 61,014 (1999). (PECO’s Supply Acquisition unit performed unbundled retail merchant services and thus the Standards applied).

⁸⁷ See, e.g., *High Island Offshore System*, 116 FERC ¶ 61,047 (2006).

⁷⁸ The term “bundled retail sales employees” means those employees of the public utility transmission provider or its affiliates who market or sell the bundled electric energy product (including generation, transmission, and distribution) delivered to the transmission provider’s firm and non-firm retail customers. Order No. 2004–A, FERC Stats. & Regs. ¶ 31,161 at P 119 n.80.

⁷⁹ *Promoting Wholesale Competition Through Open Access Non-Discriminatory Transmission Services by Public Utilities; Recovery of Stranded Costs by Public Utilities and Transmitting Utilities*, Order No. 888, FERC Stats. & Regs. ¶ 31,036, 31,781 (1996), order on reh’g, Order No. 888–A, FERC Stats. & Regs. ¶ 31,048 (1997), order on reh’g, Order No. 888–B, 81 FERC ¶ 61,248, order on reh’g, Order No. 888–C, 82 FERC ¶ 61,046 (1998), *aff’d in relevant part sub nom. Transmission Access Policy Study Group v. FERC*, 225 F.3d 667 (D.C. Cir. 2000), *aff’d sub nom. New York v. FERC*, 535 U.S. 1 (2002).

⁸⁰ *Id.*

⁸¹ *New York v. FERC*, 535 U.S. 1 at 28.

⁸² TAPS at 39–40.

⁸³ See Order No. 2004–A, FERC Stats. & Regs. ¶ 31,161 at P 127.

⁸⁴ See, e.g., *Revision of Annual Charges Assessed to Public Utilities*, 94 FERC ¶ 61,290, at 62,037 (2001). We note that the Supreme Court has described “bundled” as meaning that consumers pay a single charge that includes both the cost of

⁷⁴ 16 U.S.C. 824d(b) and 16 U.S.C. 824e(a) (emphasis added).

⁷⁵ 15 U.S.C. 717c(b) and 15 U.S.C. 717d(a) (emphasis added).

⁷⁶ Order No. 717, FERC Stats. & Regs. ¶ 31,280 at P 77 (footnote omitted).

⁷⁷ We note that the courts have held that an agency may alter its past interpretation in light of reconsideration of relevant facts and its mandate. *American Trucking Ass’n v. Atchison, Topeka & Santa Fe Ry.*, 387 U.S. 397, 416 (1967). See also *Hatch v. FERC*, 654 F.2d 825, 834 (D.C. Cir. 1981). See also *New York v. FERC*, 535 U.S. 1 at 28 (2002) (The Commission’s choice not to assert jurisdiction represents a statutorily permissible policy choice).

b. Natural Gas Industry

41. We noted in Order No. 717 that if a local distribution company (LDC) does not conduct transmission transactions with an affiliated pipeline, its off-system sales on non-affiliated pipelines are irrelevant as far as the Standards are concerned.⁸⁸ However, there may be situations where an affiliated LDC, an intrastate pipeline, and a Hinshaw pipeline could be subject to the Standards of Conduct, such as when one of these affiliates engages in off-system sales of gas that has been transported on the affiliated pipeline. In such a case, the pipeline and the affiliate (which is engaging in marketing functions) will be required to observe the Standards of Conduct by, among other things, having the marketing function employees function independently from the transmission function employees.

(i) Off-System Sales by LDCs

42. The American Gas Association (AGA), Duke Energy Corporation (Duke), National Fuel Gas Distribution Corporation and National Fuel Gas Supply Corporation (National Fuel), the New York Public Service Commission (NYPSC), and Southwest Gas Corporation (Southwest Gas) all ask the Commission to clarify that an LDC may make off-system sales on non-affiliated pipelines without being subject to the Standards.⁸⁹ Specifically, the concern raised is whether an LDC that makes off-system sales on non-affiliated pipelines would be subject to the Standards for those sales because it also conducts transmission transactions with an affiliated interstate pipeline for the purpose of making bundled retail sales or on-system sales.⁹⁰ These parties all rely on Order No. 497 and *National Fuel Gas Supply Corp.*⁹¹ to support their contention that the Commission should find that the Standards do not apply in this instance.⁹²

43. The parties argue that failing to make this clarification will have effectively expanded the Standards beyond those adopted under Order No. 497 to encompass all of an LDC's off-system sales for resale including those sales where the gas was not transported

on the affiliated interstate pipeline.⁹³ To resolve this matter, Duke suggests that the Commission either (1) revise the definition of "marketing function" in § 358.3(c)(2) of the regulations to exempt off-system sales by an LDC that do not involve the use of transmission capacity of an affiliated transmission provider; or (2) revise the applicability language of § 358.1(a) to make clear that the Standards of Conduct do not apply to an interstate pipeline's transportation of gas for an affiliate, if it "does not involve transportation of gas for the affiliate's marketing function."⁹⁴

44. Southwest Gas contends that both Order Nos. 497 and 690 excluded LDC sales from the definition of "marketing" if the gas was sold on-system to retail end-users, as well as if the gas was sold outside of its service territory as long as none of the gas sold off-system was also transported by an affiliated interstate pipeline.⁹⁵ Southwest Gas states that an LDC's sale of gas outside its retail service area in a transaction that does not involve the affiliated pipeline should not trigger the Standards nor should they be triggered if the LDC ships gas on an affiliated pipeline in other transactions for sale within the LDC's retail service territory.⁹⁶

45. If the Commission denies the request for clarification or rehearing, National Fuel requests a waiver of the Standards necessary for National Fuel Distribution Corporation to conduct off-system sales that do not involve its affiliated pipeline.⁹⁷ Similarly, the NYPSC seeks clarification that the waiver previously granted to National Fuel remains in effect pursuant to the Commission's related determination that all existing waivers relating to the Standards remain in full force and effect.⁹⁸

⁹³ See, e.g., *id.* at 11.

⁹⁴ Duke Request at 3.

⁹⁵ Southwest Gas at 9–10.

⁹⁶ *Id.* at 11–12. Southwest Gas also states in its pleading that there is no evidence that regulated LDCs could abuse their relationship with an affiliated pipeline if the LDC sells gas outside its retail service area and none of the off-system gas is transported on an affiliated pipeline. Southwest Gas at 2. Southwest Gas argues that Order No. 717 improperly expands the applicability criteria from those in effect under Order No. 497 to cover any transportation by a pipeline for an affiliate that engages in marketing functions even if none of those transactions involved transportation by the affiliate pipeline. *Id.*

⁹⁷ National Fuel at 31. National Fuel also requests a waiver of the Standards as they may pertain to *de minimis* sales necessary to remain in balance. This waiver request is addressed *infra*.

⁹⁸ NYPSC at 7. The NYPSC disputes the interpretation of *National Fuel Gas Supply Corp.*, 64 FERC ¶ 61,192 (1993), as the granting of a waiver request. However, if the Commission concludes that a waiver was granted in that proceeding, the NYPSC contends that the waiver should be continued.

46. Finally, AGA states that in Order No. 717, the Commission exempted from the definition of "marketing functions" as applied to natural gas pipelines "sales by an intrastate natural gas pipeline, by a Hinshaw interstate pipeline exempt from the Natural Gas Act, or by a local distribution company making an on-system sale."⁹⁹ AGA states that the comma placements in separating each entity suggests that only an LDC's on-system sales are exempt and that all of a Hinshaw pipeline's sales are exempt.¹⁰⁰ AGA requests that the Commission clarify whether it intended to exempt all of a Hinshaw pipeline's sales or only its on-system sales.¹⁰¹

Commission Determination

47. In Order No. 717, the Commission stated that if a pipeline does not conduct transmission transactions with an affiliate that engages in marketing functions, it is not subject to the Standards under § 358.1(a).¹⁰² We further explained that if an LDC does not conduct transmission transactions with an affiliated interstate pipeline, its off-system sales on an unaffiliated pipeline are irrelevant insofar as the Standards are concerned.¹⁰³

48. Consistent with *National Fuel Gas Supply Corp.*,¹⁰⁴ we further clarify that an LDC making off-system sales of gas that has been transported on non-affiliated pipelines is not subject to the Standards of Conduct if it conducts transmission transactions with an affiliated interstate pipeline for the purpose of making bundled retail sales or on-system sales. In light of this clarification we reject Duke Energy's suggested amendments to the Standards. We also reject National Fuel's request for a waiver of the Standards because it has been rendered moot.

49. We agree with AGA that the comma placements separating each entity in the definition of "marketing functions" in § 358.3(c) creates confusion. The Commission clarifies that we intended to exempt all on-system sales by an intrastate natural gas pipeline, by a Hinshaw interstate pipeline exempt from the NGA, or by a local distribution company and we will accordingly revise § 358.3(c)(2)(v).¹⁰⁵

⁹⁹ AGA Request for Clarification or Rehearing at 14 (quoting 18 CFR 358.3(c)(2)(v)).

¹⁰⁰ *Id.* at 14.

¹⁰¹ *Id.*

¹⁰² Order No. 717, FERC Stats. & Regs. ¶ 31,280 at P 91.

¹⁰³ *Id.*

¹⁰⁴ 64 FERC ¶ 61,192 (1993).

¹⁰⁵ The change to include a local distribution company operating under section 7(f) of the Natural Gas Act in 18 CFR 358.3(c)(2)(v) is discussed *infra*.

⁸⁸ Order No. 717, FERC Stats. & Regs. ¶ 31,280 at P 91.

⁸⁹ AGA Nov. 17, 2008 Request for Clarification or Rehearing at 8; Duke Nov. 17, 2008 Request for Rehearing or Clarification at 4; National Fuel Nov. 17, 2008 Motion for Clarification or Rehearing or, in the Alternative, Request for Limited Waiver at 7–8; NYPSC Nov. 17, 2008 Request for Rehearing or Clarification at 3–4; and Southwest Gas at 9–10.

⁹⁰ See, e.g., AGA Request at 4.

⁹¹ 64 FERC ¶ 61,192 (1993).

⁹² See, e.g., AGA at 9 (citing *National Fuel Gas Supply Corp.*).

(ii) Sales From Own Production

50. The American Public Gas Association (APGA) objects to the Commission's determination to exclude from the definition of "marketing functions" the sale of natural gas from a seller's own production and from a seller's own gathering or processing facilities.¹⁰⁶ APGA states that there is no logical, legal or factual basis for including within the Standards affiliated sellers of third party gas, but excluding from the rule the pipeline itself and affiliated sellers where they are selling from their own production.¹⁰⁷

51. APGA argues that because the Commission has adopted an employee functional approach, the available evidence of actual abuse between sales employees and affiliated transmission providers fully supports a rule requiring their separation.¹⁰⁸ APGA states that while these cases may not have been sufficient under the corporate separation approach to the Standards under Order No. 2004 and that the court reviewed in *National Fuel*, under the employee functional approach, certain cases of abuse support the discrete proposition that all employees who actively and personally engage on a day-to-day basis in natural gas sales should be prohibited from obtaining non-public information about the day-to-day transmission operations of affiliated pipelines. APGA asserts that the origin of the natural gas involved should have no bearing on the issue whatsoever.¹⁰⁹

52. Calypso U.S. Pipeline LLC and Calypso LNG LLC (Calypso) ask the Commission to further clarify the term "seller's own production" in § 358.3(c)(3). Specifically, Calypso contends that the exemption should encompass foreign-sourced gas regardless of whether the transmission provider owns the mineral rights at the foreign wellhead or acquires ownership of the gas at the outlet of the liquefaction facility, or on board a liquefied natural gas (LNG) vessel, so long as it owns the gas when it is introduced into the transmission provider's facilities as the only gas that the transmission provider is transporting.¹¹⁰ Calypso interprets the term "own production" to mean gas owned by the transmission provider's marketing affiliate rather than gas that was owned when still in the ground or

was extracted by the transmission provider (or its marketing affiliate).¹¹¹

53. To the extent that the Commission intended to confine the exemption to foreign-sourced gas that was owned by the transmission provider's marketing affiliate at the foreign wellhead or some other point upstream being introduced into the transmission provider's facilities, then Calypso seeks rehearing on this point.¹¹² Calypso asserts that when the only gas the transmission provider transports is owned by the transmission provider's marketing affiliate, the transmission provider should be exempt from the requirement that its transmission function employees function independently from its marketing function employees. Calypso argues that this result would be the same as the case where the only gas flowing was the domestic production of the transmission provider.¹¹³

54. Calypso states that the key factor in applying this exemption is not ownership at the wellhead, but rather (i) the absence of someone against whom the transmission provider can discriminate, and (ii) the proposition that the Commission "cannot impede vertical integration between a pipeline and its affiliates without 'adequate justification.'" ¹¹⁴

Commission Determination

55. We deny APGA's request for rehearing concerning the Commission's determination to exclude from the definition of "marketing functions" the sale of natural gas from a seller's own production and from a seller's own gathering and processing facilities. In Order No. 497-A, the Commission excluded from the scope of the rule "[p]roducers, gatherers or processors, acting in their traditional roles, that sell gas solely from their own production, gathering, or processing facilities."¹¹⁵ In excluding these sellers of gas from the scope of the rule, the Commission explained that these entities do not act within the scope of the term "marketing" as it is used in the rule because these "entities are acting in the roles that their names imply"¹¹⁶ rather than engaging in "marketing functions." We do not see, nor has APGA demonstrated, how these entities' roles have changed since Order No. 497 that would require the Commission to now conclude that they are engaging in

marketing functions for the purposes of the Standards of Conduct.

56. In Order No. 2004-A, the Commission also found that the roles of gatherers or processors did not support their inclusion as energy affiliates subject to the standards of conduct. Specifically, the Commission stated in Order No. 2004-A that if a gatherer or processor merely provides gathering or processing services, only purchases natural gas to supply operational needs, and does not engage in other transmission-related activities, then it is not an energy affiliate subject to the standards of conduct.¹¹⁷ Moreover, we found that "when gatherers and processors engage only in gathering and processing, they provide services to wholesale market participants but do not compete with them."¹¹⁸

57. We also do not agree with APGA that the adoption in Order No. 717 of an employee functional approach from a corporate functional approach dictates that we eliminate these exclusions from the definition of "marketing functions." The adoption of the employee functional approach in Order No. 717 is simply a reversion to the employee functional approach in effect under Order No. 497. Over the Commission's decades-long experience implementing standards of conduct, the Commission has not found a pattern of abuse concerning sales of natural gas solely from a seller's own production or a seller's own gathering and processing facilities that would necessitate a change to this exclusion to the "marketing functions" definition, even under the employee functional approach.¹¹⁹ The Commission has addressed through its enforcement actions, including civil penalties, the few cases of sales personnel and affiliate transmission providers improperly sharing non-public transmission function information.¹²⁰

58. Notwithstanding the fact that the Standards of Conduct do not govern the relationship between a transmission provider and producers, gatherers or processors, acting in their traditional roles, that sell gas solely from their own

¹¹⁷ Order No. 2004-A, FERC Stats. & Regs. ¶ 31,161 at P 97.

¹¹⁸ *Id.*; see also Order No. 2004-B, FERC Stats. & Regs. ¶ 31,166 at P 77.

¹¹⁹ The Commission has not found evidence of undue preference that was exclusively a result of sales of natural gas solely from a seller's own production or its own gathering or processing facilities.

¹²⁰ See, e.g., *Dominion Resources, Inc.*, 108 FERC ¶ 61,110 (2004) (Hackberry); *The Williams Companies, Inc.*, 111 FERC ¶ 61,392 (2005); *Idaho Power Co.*, 103 FERC ¶ 61,182 (2003); *Cleco Corp.*, 104 FERC ¶ 61,125 (2003); and *Transcontinental Gas Pipe Line Corp.*, 102 FERC ¶ 61,302 (2003).

¹⁰⁶ APGA Nov. 17, 2009 Request for Rehearing at 4.

¹⁰⁷ *Id.* at 5.

¹⁰⁸ *Id.* at 6.

¹⁰⁹ *Id.*

¹¹⁰ Calypso Nov. 17, 2009 Request for Clarification or Rehearing at 4.

¹¹¹ *Id.*

¹¹² *Id.* at 5.

¹¹³ *Id.*

¹¹⁴ *Id.* at 7.

¹¹⁵ Order No. 497-A, FERC Stats. & Regs. ¶ 30,868 at P 12 (footnotes omitted).

¹¹⁶ *Id.*

production, gathering, or processing facilities, we note that section 4 of the Natural Gas Act prohibits a pipeline from granting any undue preference or advantage to any person or subjecting any person to any undue prejudice or disadvantage.¹²¹ For all of the above reasons, we deny APGA's request to change the "marketing functions" exclusions in § 358.3(c)(2).

59. We grant Calypso's request that we clarify the term "seller's own production" in § 358.3(c)(3). In *Hackberry*, we adopted a light-handed regulatory approach to LNG terminals,¹²² viewing LNG import terminals as analogous to production facilities.¹²³ This revised approach to LNG regulation was subsequently reflected in EPAAct 2005.¹²⁴ In light of our view that LNG import terminals are analogous to production facilities, we clarify that the exemption encompasses foreign sourced gas regardless of whether the seller owns the mineral rights at the foreign wellhead or acquires ownership on board an LNG vessel, so long as it owns the gas before it enters the transmission provider's transmission facilities and the gas is the only gas the transmission provider is transporting. In this scenario, there is no one for the transmission provider to discriminate against.

(iii) Asset Management Agreements

60. Southwest Gas asserts that the Commission failed to address (1) the applicability of the Standards to pipelines affiliated with shippers releasing capacity to asset managers under asset management agreements, and (2) the question of whether NGA section 7(f) companies are within the scope of the LDC exemption.¹²⁵ Southwest Gas seeks clarification that where a party releases capacity to an asset manager under an asset management agreement where there is also an assignment of gas supply, the releasing party under the asset management agreement does not engage in a marketing function and its affiliated pipelines are not subject to the Standards.¹²⁶

61. Southwest Gas contends that even where a party to an asset management agreement assigns gas supply, there is no basis for the party's participation in

the asset management agreement to trigger the Standards for a pipeline affiliated with that releasing party.¹²⁷ Southwest Gas further asserts that there is "no record evidence or a demonstrated theoretical threat to bring releasing parties under an asset management agreement and their affiliated pipelines within the scope of the Standards merely by virtue of their participation in an asset management agreement."¹²⁸

Commission Determination

62. In Order Nos. 712 and 712-A,¹²⁹ the Commission revised its capacity release regulations to facilitate the use of asset management agreements. The Commission found that these agreements were in the public interest because they are beneficial to numerous market participants and to the market in general.¹³⁰ In the asset management agreement context, the releasing shipper is not releasing unneeded capacity but capacity it needs to serve its own supply function. Releasing shippers are thus releasing capacity for the primary purpose of transferring the capacity to entities that they perceive as having greater skill and expertise in both purchasing low cost gas supplies and maximizing the value of the capacity when it is not needed to meet the releasing shipper's gas supply needs. Essentially, asset management agreements entail a releasing shipper transferring capacity to a third party expert who will perform the functions that the releasing shipper would normally have to do itself, *i.e.* purchase gas supplies and releasing capacity or making bundled sales when the releasing shipper does not need the capacity to satisfy its own needs.¹³¹

63. In Order No. 717, we clarified that under the Independent Functioning Rule and the No Conduit Rule, it would be the employees of the asset manager acting as agents or contractors for the pipeline or LDC, who would qualify as marketing function employees after the asset management arrangement was concluded and not the employees of the releasing party.¹³² Therefore, we grant Southwest Gas' request for clarification and find that the releasing shipper is not performing a marketing function when

it assigns gas supply pursuant to an asset management agreement. However, if the specific asset management agreement leaves the releasing shipper any ability to conduct sales for resale or provides that the releasing shipper is to retain control of the transactions entered into by the asset manager, the releasing shipper would remain subject to the Independent Functioning Rule with regard to that specific agreement.

(iv) Balancing

64. In Order No. 717, the Commission exempted from the definition of marketing functions incidental purchases or sales of natural gas to operate interstate natural gas pipeline transmission facilities. AGA requests that the Commission clarify that an affiliate of an interstate pipeline is not engaged in "marketing functions" under § 358.3(c)(2)(ii) to the extent that such affiliate makes incidental purchases or sales of natural gas to remain in balance under applicable pipeline tariffs.¹³³ AGA believes that the scope of the exemption should not be limited to the pipeline itself because there is a counterparty (often a shipper) for each sale and purchase the pipeline makes to keep its system in balance.¹³⁴ AGA contends that such purchases and sales do not present any significant opportunity for a pipeline to unduly discriminate in favor of an affiliate because the affiliate must follow the pipeline's cash-out and balancing tariff provisions.

65. Both National Fuel and INGAA request that the Commission clarify that *de minimis* off-system sales that are related to an LDC's balancing requirements are not captured in the definition of marketing function.¹³⁵ INGAA requests that the Commission either reestablish the separate exemption for sales by an affiliate that are made in order to remain in balance under a pipeline tariff or operational balancing agreement, or explicitly clarify that § 358.3(c)(2)(ii) covers such exemptions.¹³⁶ In the alternative, National Fuel requests rehearing to revise the regulations to provide specifically that *de minimis* off-system sales that are in connection with the resolution of the LDC's inadvertent

¹²¹ 15 U.S.C. 717b-1.

¹²² *Hackberry LNG Terminal L.L.C.*, 101 FERC ¶ 61,294 (2002), *order issuing certificates and granting rehearing*, 104 FERC ¶ 61,269 (2003). Some LNG terminals continue to allow open access service pursuant to Part 284.

¹²³ See *Hackberry*, 101 FERC ¶ 61,294 at P 27.

¹²⁴ See 15 U.S.C. 717b.

¹²⁵ Southwest Gas at 5.

¹²⁶ *Id.* at 6.

¹²⁷ *Id.* at 8.

¹²⁸ *Id.* at 9.

¹²⁹ *Promotion of a More Efficient Capacity Release Market*, Order No. 712, 73 FR 37058 (June 30, 2008), FERC Stats. & Regs. ¶ 31,271 (2008), *order on rehearing*, Order No. 712-A, 73 FR 72692 (Dec. 1, 2008), FERC Stats. & Regs. ¶ 31,284 (2008).

¹³⁰ Order No. 712-A, FERC Stats. & Regs. ¶ 31,284 at P 68 and P 71.

¹³¹ *Id.* P 70.

¹³² Order No. 717, FERC Stats. & Regs. ¶ 31,280 at P 97.

¹³³ AGA at 13. As noted above, we defined marketing functions for pipelines and their affiliate as "the sale for resale in interstate commerce, or the submission of offers to sell in interstate commerce, of natural gas," subject to several exclusions including an exclusion for incidental purchases or sales of natural gas to operate interstate natural gas pipeline transmission facilities. See Order No. 717, FERC Stats. & Regs. ¶ 31,280 at P 83.

¹³⁴ AGA at 13.

¹³⁵ National Fuel at 11-12.

¹³⁶ INGAA at 12.

imbalances pursuant to pipeline tariffs, do not fit within the definition of “marketing function.”¹³⁷

66. INGAA also requests clarification that the § 358.3(c)(2)(ii) incidental exemption applies to LNG terminals.¹³⁸ INGAA states that the same general reasoning that justifies the operational sales exemption for pipelines and their affiliates should apply to LNG terminals.¹³⁹

Commission Determination

67. We clarify that an affiliate of an interstate pipeline is not engaged in “marketing functions” under § 358.3(c)(2)(ii) to the extent that such affiliate makes incidental purchases or sales of natural gas to remain in balance under applicable pipeline tariffs. We agree with AGA that these transactions do not present a significant opportunity for undue discrimination. This clarification is consistent with our finding in Order No. 717 that, in the case of interstate pipelines and their affiliates, incidental purchases or sales of natural gas to operate interstate natural gas pipeline transmission facilities do not constitute a marketing function.¹⁴⁰ Furthermore, we note that under the previous regulations adopted in Order No. 2004, we found that an energy affiliate did not include an interstate pipeline that makes incidental purchases or sales of *de minimis* volumes of natural gas to remain in balance under applicable pipeline tariff requirements.¹⁴¹

68. In response to National Fuel and INGAA, the Commission clarifies that *de minimis* off-system sales that are related to an LDC’s balancing requirements are not included in the definition of marketing function. As we stated in Order No. 2004–A, “an LDC serving only its on-system customers must comply with pipeline balancing requirements and may be required to buy or sell *de minimis* [sic] quantities of natural gas in the wholesale commodity market, purchase short-term park and loan and storage services, buy or sell imbalances in the pipeline’s cash out mechanism, or take other steps to meet pipeline tariff balancing tolerances on a daily or monthly basis. LDCs with limited participation in wholesale markets to satisfy these needs will continue to be exempt from the definition of Energy Affiliate as long as they are not participating in the other

activities described in § 358.3(d)”¹⁴² *i.e.* marketing activities. While the Commission has eliminated the concept of an energy affiliate, the rationale and its application to marketing activities of LDCs remain unchanged. Accordingly, we clarify that the exclusion in § 358.3(c)(2)(ii) includes *de minimis* off-system sales that are related to an LDC’s balancing requirements under interstate pipeline tariffs.

69. We deny INGAA’s request for clarification regarding LNG terminals and the “incidental exemption.” INGAA has not explained how an incidental exemption would be applied to an LNG facility.

(v) Other

70. MidAmerican asks the Commission to clarify that employees of an electric public utility purchasing and selling natural gas for generation or local distribution company functions are not marketing function employees of the electric public utility.¹⁴³ The Commission addressed this issue in Order No. 717, finding that the question was rendered moot by the exclusion of purchases of gas from the definition of marketing function.¹⁴⁴ However, MidAmerican states that gas acquisition at retail for generation usually involves incidental sales of unneeded gas supply and therefore, the Commission must address this issue directly.¹⁴⁵ MidAmerican states that while an LDC employee may not be considered to engage in a marketing function at a pipeline if the LDC is excluded by § 358.3(c)(2), there is no similar exemption of LDCs under the definition of the electric marketing function and there is no evidence to suggest that a gas acquisition employee is privy to electric transmission function information.¹⁴⁶

71. Southwest Gas requests that the Commission clarify the phrase “the submission of offers to sell in interstate commerce” in the definition of natural gas marketing function activities.¹⁴⁷ Southwest Gas explains that the submission of an offer sweeps within its scope not only sales of natural gas in interstate commerce but also activity between market participants prior to the actual sales agreement becoming effective. Southwest Gas believes that in application “submission of offers” is

unclear.¹⁴⁸ Southwest Gas requests clarification of the definition of “marketing functions” to reflect only the sale of gas in interstate commerce.¹⁴⁹

72. The Williams Companies, Inc. (Williams) request clarification that the exclusion in § 358.3(c)(2)(iii) for “sales of natural gas solely from a seller’s own production” will be interpreted consistent with the similar exclusion adopted in Order No. 497–A as including “situations in which a producer is selling gas that it owns or is selling gas of other interest owners in the same well and reservoir to the extent that the producer has contractual authority to sell such gas.”¹⁵⁰ Williams states that this clarification is consistent with the Commission’s intent, as expressed in Order No. 690–A, to “track the scope of the standards of conduct requirements for natural gas transmission providers in Order No. 497”¹⁵¹ and to carry forward the historical exclusions in Order No. 717.¹⁵²

73. Alternatively, should the Commission choose not to clarify the exclusion in § 358.3(c)(iii) as described above, Williams requests rehearing, and claims that the Commission has provided no rationale to support interpreting the exclusion in a manner differently from that which was in effect under Order No. 497–A.¹⁵³ Williams argues that the Commission should, therefore, grant rehearing and provide that the exclusion in § 358.3(c)(2)(iii) includes sales of gas of other interest owners in the same well and reservoir to the extent that the producer has contractual authority to sell such gas.¹⁵⁴

Commission Determination

74. We deny MidAmerican’s request for clarification regarding electric public utility employees selling unneeded natural gas supply originally purchased for generation or local distribution company functions. MidAmerican asks that these employees not be considered marketing function employees. However, MidAmerican does not provide adequate support for the broad exemption requested. Moreover, MidAmerican does not explain the

¹⁴⁸ *Id.*

¹⁴⁹ *Id.*

¹⁵⁰ Williams Nov. 17, 2009 Request for Clarification or Rehearing at 7.

¹⁵¹ *Standards of Conduct for Transmission Providers*, Order No. 690–A, *order on clarifications and rehearing*, FERC Stats. & Regs. ¶ 31,243, at P 13 (2007).

¹⁵² *Standards of Conduct for Transmission Providers*, FERC Stats. & Regs. ¶ 32,630, at P 36 (2008).

¹⁵³ Williams at 8–9.

¹⁵⁴ *Id.* at 9.

¹³⁷ National Fuel at 25.

¹³⁸ INGAA at 13.

¹³⁹ *Id.*

¹⁴⁰ Order No. 717, FERC Stats. & Regs. ¶ 31,280 at P 83.

¹⁴¹ Order No. 2004, FERC Stats. & Regs. ¶ 31,155 at P 77.

¹⁴² Order No. 2004–A, FERC Stats. & Regs. ¶ 31,161 at P 61.

¹⁴³ MidAmerican Request for Rehearing or Clarification at 15.

¹⁴⁴ Order No. 717, FERC Stats. & Regs. ¶ 31,280 at P 103.

¹⁴⁵ MidAmerican at 15.

¹⁴⁶ *Id.* at 16.

¹⁴⁷ Southwest Gas at 13.

circumstances under which the exemption should apply. For example, MidAmerican does not explain how “unnecessary” should be defined.

75. We deny the request for clarification by Southwest Gas to remove “the submission of offers to sell in interstate commerce” from the definition of natural gas marketing function activities so that it reflects only the sale of gas in interstate commerce. The submission of an offer to sell is an indication that a party intends to sell. As such, marketing function employees should not be in contact with transmission function employees once they have submitted offers to sell.

76. The Commission grants the request for clarification by Williams and states that the exclusion in § 358.3(c)(2)(iii) for “sales of natural gas solely from a seller’s own production” is consistent with the similar exclusion adopted in Order No. 497–A that includes “situations in which a producer is selling gas that it owns or is selling gas of other interest owners in the same well and reservoir to the extent that the producer has contractual authority to sell such gas.”¹⁵⁵ As we stated in Order No. 497–A, this does not mean that such entities can never be considered to be marketers of gas as the term is used in the Standards of Conduct. If a producer sells gas that was produced by another, it is acting as a marketer of the gas.¹⁵⁶ Furthermore, a gatherer or processor that sells gas from facilities other than its own is a marketer.¹⁵⁷

4. Marketing Function Employees

77. Wisconsin Electric seeks clarification as to whether an employee in the legal, finance or regulatory division of a jurisdictional entity, whose intermittent day-to-day duties include the drafting and redrafting of non-price terms and conditions of, or exemptions to, umbrella agreements would be considered a “marketing function employee” under the standards.¹⁵⁸

78. Wisconsin Electric asks the Commission to provide guidance with respect to which types of activities it considers to be “day-to-day” activities of a marketing function employee.¹⁵⁹ Specifically, Wisconsin Electric requests that the Commission clarify whether individuals responsible for contract administration are “marketing function employees” under the rule and whether

the preparation of monthly or annual requests for financial transmission rights and auction revenue rights constitutes “day-to-day” activities pursuant to the rule.¹⁶⁰

79. EEI understands that an officer may disapprove a power sales contract without becoming a marketing function employee.¹⁶¹ However, EEI requests clarification as to whether the officer is permitted to explain why a contract is being disapproved.¹⁶² EEI argues that the ability to provide such overall feedback, which may effectively become general parameters for contract renegotiation, is important for efficient discharge of fiduciary duties and an important part of corporate governance.¹⁶³

Commission Determination

80. The Commission clarifies that an employee in the legal, finance or regulatory division of a jurisdictional entity, whose intermittent day-to-day duties include the drafting and redrafting of non-price terms and conditions of, or exemptions to, umbrella agreements is a “marketing function employee.” “Marketing functions” are not limited to only price terms and conditions of a contract, because non-price terms and conditions of a contract could contain information that an affiliate could use to its advantage. For example, delivery or hub locations in a contract are non-price terms that could be used to favor an affiliate. In addition, negotiated terms and conditions could affect the substantive rights of the parties. For this reason, we decline to make a generic finding to limit “marketing functions” to only price terms and conditions, but will consider waiver requests concerning an employee whose intermittent duties involve drafting non-price terms and conditions.

81. Wisconsin Electric requests that the Commission clarify whether individuals responsible for contract administration are “marketing function employees” under the rule. As stated in Order No. 717, the “development of general negotiating parameters for wholesale contracts” is not considered a “day-to-day” activity that characterizes a transmission function or the duties of a marketing function employee.¹⁶⁴ However, if the employee responsible for contract administration “regularly carries out or supervises * * * or is

actively and personally engaged” in the negotiation of the contracts, then he or she is considered a marketing function employee.¹⁶⁵ Because Wisconsin Electric has not provided any information about the duties of its employee responsible for contract administration, the Commission is unable to provide any further clarification.

82. Wisconsin Electric also requests clarification concerning employees who prepare monthly or annual requests for financial transmission rights and auction revenue allocations to hedge the costs of serving load. The Commission states that if these employees are not actively and personally engaged in sales for resale of these products, but only involved in purchases through requests for financial transmission rights and auction revenue rights allocations, then they are not marketing function employees.

83. EEI requests that we clarify that a supervisor is not engaged in a marketing function when that supervisor explains why a contract is being disapproved. As stated in Order No. 717, a supervisor is not engaged in the marketing function activity, if that supervisor is “simply signing off on a deal negotiated or proposed by someone else, and is not providing input into the negotiations.”¹⁶⁶ Similarly, we clarify that as long as the supervisor is not actively and personally engaged on a day-to-day basis in the contract negotiations and is simply providing an explanation concerning the disapproval of a contract, the supervisor is not engaged in a marketing function. However, in this scenario, the supervisor remains subject to the No Conduit Rule.

5. Long-Range Planning, Procurement and Other Interactions

84. MidAmerican asks the Commission to delete the communication bars and acknowledge that communications between marketing and transmission function employees are permitted, but must comply with the Standards.¹⁶⁷ MidAmerican argues that the Commission has too narrowly described and too broadly restricted communications between transmission and marketing function employees.¹⁶⁸ MidAmerican asserts that there are circumstances that may give rise to a need for business communication

¹⁵⁵ Order No. 497–A, FERC Stats. & Regs. ¶ 30,868 at 31,591 n.19.

¹⁵⁶ *Id.* at 31,591–2.

¹⁵⁷ *Id.*

¹⁵⁸ Wisconsin Electric Nov. 17, 2009 Request for Clarification at 6.

¹⁵⁹ *Id.* at 7.

¹⁶⁰ *Id.* at 8.

¹⁶¹ EEI at 9–10.

¹⁶² *Id.*

¹⁶³ *Id.*

¹⁶⁴ Order No. 717, FERC Stats. & Regs. ¶ 31,280 at P 122.

¹⁶⁵ *See id.* P 117.

¹⁶⁶ Order No. 717, FERC Stats. & Regs. ¶ 31,280 at P 119.

¹⁶⁷ MidAmerican at 14.

¹⁶⁸ *Id.*

between these groups that would not in any way impute restricted non-public transmission function information such as human resources matters.¹⁶⁹

85. EEI notes that there is a range of business-related activities that have nothing to do with transmission or marketing functions, such as meetings to discuss long term strategic corporate goals, benefit options, safety training, leadership development, and charity drives.¹⁷⁰ EEI requests clarification that the scope of permitted interactions extends to these types of activities.¹⁷¹ EEI requests clarification that meetings that include transmission function and marketing function employees, but do not relate to transmission or marketing functions, are not barred under the Standards, but remain subject to the No Conduit Rule.¹⁷²

86. EEI suggests that there are other areas that may relate tangentially to transmission or marketing functions for which meetings should be allowed.¹⁷³ These include design and implementation of FERC or other compliance programs, and investigation and remediation of potential violations.¹⁷⁴ Accordingly, EEI requests clarification that joint participation in public or quasi-public meetings is permitted, and that joint meetings regarding legal, regulatory, rate, compliance, enforcement, or other corporate or business matters are permitted, subject to the No Conduit Rule.¹⁷⁵

87. Western Utilities Compliance Group (Western Utilities)¹⁷⁶ also seeks clarification that certain joint meetings and communications between marketing function employees and transmission function employees are permissible. Specifically, Western Utilities requests that we clarify that the Standards do not prohibit joint meetings and communications that do not violate the separation of functions requirement provided in 18 CFR 358.5(b) and that do not include any disclosure of non-public transmission function information to marketing function

employees.¹⁷⁷ Western Utilities contends that previously only joint meetings and communications about transmission related matters were prohibited and that it has established safeguards and procedures to ensure that no sharing of non-public transmission function information occurs at these meetings.¹⁷⁸ According to Western Utilities, examples of the types of joint meetings and communications that should be permitted under the Standards include corporate meetings and training,¹⁷⁹ the development process for reliability standards, ISO/RTO issues, disaster/outage preparedness training,¹⁸⁰ and joint participation in FERC and State regulatory and compliance functions.¹⁸¹

88. INGAA also discusses a variety of other examples of the types of joint meetings that should be permitted under the Standards, including affiliate participation in regulatory or industry proceedings or conferences;¹⁸² pipeline sponsored meetings with customers;¹⁸³ and pipeline marketing.¹⁸⁴ AGA also believes the Independent Functioning Rule of the Standards of Conduct should not be interpreted to preclude business-related meetings and discussions between transmission function employees and marketing function employees where non-public transmission function information will not be disclosed.¹⁸⁵

Commission Determination

89. The Commission clarifies that certain communications between marketing and transmission function

employees are permitted. Specifically, the Commission clarifies that meetings including both transmission function and marketing function employees are not barred under the Standards of Conduct as long as the meetings do not relate to transmission or marketing functions. However, the No Conduit Rule still applies to these meetings.

90. We decline to provide a generic clarification regarding EEI's request that we allow meetings that "relate tangentially to transmission or marketing functions," as this phrase is too nebulous for us to determine the extent to which non-public transmission function information might be disclosed at these meetings. However, we do clarify that so long as non-public transmission function information is not disclosed between transmission and marketing function employees as part of the development process for reliability standards, then joint meetings including both transmission and marketing function employees are permissible. Similarly, joint meetings including both transmission and marketing function employees to discuss RTO and ISO issues are permissible if non-public transmission function information is not disclosed between transmission and marketing function employees. Furthermore, we clarify that transmission function employees and marketing function employees may jointly participate in regulatory and compliance functions, including Federal Energy Regulatory Commission compliance activities, as long as these discussions do not include any disclosure of non-public transmission function information.

91. However, we decline the Western Utilities' request that we find that joint meetings for disaster/outage preparedness training fit within the permitted interactions "to maintain or restore operation of the transmission system or generating units, * * *" as described in § 358.7(h)(2). The exclusion described in § 358.7(h)(2) is limited to true emergency situations, rather than preparation for a disaster. However, we clarify that joint meetings including both transmission and marketing function employees for disaster/outage preparedness training are permissible as long as these employees do not share non-public transmission function information. Furthermore, the Commission will consider on a case-by-case basis requests for waiver of this prohibition against joint meetings for disaster/outage preparedness training during which non-public transmission function information will be discussed.

¹⁷⁷ Western Utilities at 5. INGAA supports this request for clarification. See INGAA August 4, 2009 Answer at 4.

¹⁷⁸ *Id.* at 6.

¹⁷⁹ *Id.* at 8. These include award ceremonies, community service activities, training on leadership, EEO safety and ethics as well as utility-wide management meetings. INGAA states that this category of meetings would also apply to interstate pipelines. INGAA Answer at 4.

¹⁸⁰ *Id.* at 9. Essentially, Western Utilities' question is whether these meetings and communications would be permitted under the exception regarding meetings "to maintain or restore operation of the transmission system or generating units." See 18 CFR 358.7(h)(2).

¹⁸¹ *Id.* INGAA states that this category of meetings also would apply to interstate pipelines. INGAA Answer at 4.

¹⁸² INGAA Answer at 7.

¹⁸³ *Id.* INGAA provided examples of the topics at such meetings including changes to business processes, an upcoming tariff filing or the status of on-going regulatory proceedings.

¹⁸⁴ *Id.* at 8. According to INGAA, this involves marketing the pipeline's services, not gas marketing. These meetings would include discussions of the affiliate's own contracts, sales presentations involving posted available capacity or expansion projects and services.

¹⁸⁵ AGA Sept. 11, 2009 Supplemental Comments at 4.

¹⁶⁹ *Id.*

¹⁷⁰ EEI at 7.

¹⁷¹ *Id.* at 8.

¹⁷² *Id.*

¹⁷³ *Id.*

¹⁷⁴ *Id.*

¹⁷⁵ *Id.* at 9.

¹⁷⁶ Western Utilities is comprised of Arizona Public Service Company, Avista Corporation, El Paso Electric Company, Idaho Power Company, Pacific Gas and Electric Company, PacifiCorp, Portland General Electric Company, Puget Sound Energy, Southern California Edison Company, and Tucson Electric Power Company.

92. With regard to the examples of joint meetings suggested by INGAA, we reiterate that so long as non-public transmission function information is not disclosed between transmission and marketing function employees, the meetings are permissible. If INGAA or another entity has a concern about whether the meeting would run afoul of the Standards of Conduct, then the entity should apply for a waiver in advance.

C. The No Conduit Rule

93. In Order No. 717, we continued the no conduit prohibition of the then existing Standards, but modified the rule to encompass only marketing function employees. The No Conduit Rule prohibits employees of a transmission provider from disclosing non-public transmission function information to the transmission provider's marketing function employees.¹⁸⁶ Contractors, consultants, agents, marketing function employees of an affiliate are covered by this prohibition.¹⁸⁷

94. Wisconsin Electric states that as currently written, the text of § 358.6 prohibits the disclosure of non-public transmission function information to any of the transmission provider's "marketing function employees."¹⁸⁸ Wisconsin Electric contends that the Standards of Conduct do not extend the prohibition to the "marketing function employees" of the transmission provider's affiliate.¹⁸⁹ Wisconsin Electric requests that the Commission clarify that this omission was intentional.¹⁹⁰

95. Wisconsin Electric further states that it is unclear whether the Commission intended the No Conduit Rule in § 358.6(b) to require that the employees, contractors, consultants or agents of an affiliate of a transmission provider that is engaged in marketing functions be prohibited from disclosing non-public transmission function information to any of the transmission provider's "marketing function employees" or whether the Commission intended only to proscribe the activities of employees, contractors, consultants or agents of an affiliate of a transmission provider that are engaged in transmission functions from disclosing non-public transmission function information to any of the transmission

provider's "marketing function employees."¹⁹¹

96. Additionally, Wisconsin Electric notes that § 358.8(b)(2) does not extend the requirement to distribute the written procedures in § 358.7(d) to the transmission provider's affiliates.¹⁹² Wisconsin Electric requests clarification that the omission was intentional.¹⁹³

Commission Determination

97. Wisconsin Electric contends that as currently written, the No Conduit Rule does not prohibit employees of a transmission provider from disclosing non-public transmission function information to marketing function employees of a transmission provider's affiliate. That is not the case. The No Conduit Rule prohibits disclosure of non-public transmission function information to any of the "marketing function employee[s]" of the transmission provider or its affiliate. As previously stated in Order No. 717, "[m]arketing function employees are defined in § 358.3(d) to include employees, contractors, consultants or agents not only of the transmission provider, but also of an affiliate of the transmission provider."¹⁹⁴ Therefore, the No Conduit Rule extends to "marketing function employee[s]" of the transmission provider's affiliate. For this same reason, Wisconsin Electric misunderstands the scope of the Implementation Requirements in § 358.8(b)(2). Because "marketing function employee" includes an employee of "an affiliate of a transmission provider," the Implementation Requirements in § 358.8(b)(2) extend its distribution requirement to include marketing function employees of the transmission provider's affiliate.

98. Wisconsin Electric asks whether the Commission intended the No Conduit Rule to prohibit employees, contractors, consultants or agents of an affiliate of a transmission provider that are engaged in transmission functions from acting as a conduit to disclose non-public transmission function information to any of the transmission provider's "marketing function employees." Wisconsin Electric's requested clarification to the No Conduit Rule would prohibit only transmission function employees from acting as a conduit. However, the No Conduit Rule generally states that a

transmission provider is prohibited from using anyone as a conduit to disclose non-public transmission function information to the transmission provider's marketing function employees. The No Conduit Rule is not simply limited to transmission function employees from acting as a conduit. Because Wisconsin Electric's clarification request would defeat the purpose of the No Conduit Rule, we decline to change the meaning of this section.

D. Transparency Rule

99. In Order No. 717, we also adopted a Transparency Rule, the provisions of which are designed to alert interested persons and the Commission to potential acts of undue preference. The previously existing posting requirements were moved to this section.¹⁹⁵

100. MidAmerican states that the rules should recognize that support employees may be employed by one transmission provider but assist other transmission providers in the same holding company without triggering a requirement for equal access to non-public transmission function information used in their jobs.¹⁹⁶ While MidAmerican does not suggest revival of the concept of shared employees, it suggests a change to the language in § 358.2(d) to clarify that transmission providers within the same holding company may have shared business functions that may exchange non-public transmission function information without the need for disclosure.¹⁹⁷

101. INGAA urges the Commission to delete, or in the alternative, amend the "General Principle" stated in § 358.2(d) that "[a] transmission provider must provide equal access to non-public transmission function information to all its transmission function customers, affiliated and non-affiliated, except in the case of confidential customer information or Critical Energy Infrastructure information" so that it conforms to the transparency rules under § 358.7.¹⁹⁸ INGAA believes that § 358.2(d) fails to recognize the disclosure exemption for specific requests for transmission service. INGAA points out that § 358.7(b) indicates that there is no obligation to disclose a marketing function employee's specific request for transmission service.¹⁹⁹ INGAA asserts

¹⁸⁶ See 18 U.S.C. 358.6.

¹⁸⁷ Order No. 717, FERC Stats. & Regs. ¶ 31,280 at P 201-02.

¹⁸⁸ Wisconsin Electric at 8.

¹⁸⁹ *Id.*

¹⁹⁰ *Id.*

¹⁹¹ *Id.*

¹⁹² *Id.* at 8-9.

¹⁹³ *Id.* at 9.

¹⁹⁴ Order No. 717, FERC Stats. & Regs. ¶ 61,280 at P 202. See also 18 CFR 358.3(d) (Marketing function employee includes an affiliate of a transmission provider).

¹⁹⁵ Order No. 717, FERC Stats. & Regs. ¶ 61,280 at P 205.

¹⁹⁶ MidAmerican at 11.

¹⁹⁷ *Id.* at 12.

¹⁹⁸ INGAA at 9.

¹⁹⁹ *Id.*

that § 358.2(d) can be read broadly to suggest that all discussion between a transmission function employee and an employee of an affiliate who is not a marketing function employee must be disclosed if it is non-public transmission function information.²⁰⁰

102. National Fuel asks that the Commission remove or modify the new “equal access” principle set out at § 358.2(d) by limiting its scope to non-public transmission information provided to marketing function employees, and eliminating its confusing partial list of exceptions.²⁰¹ National Fuel argues that because its applicability is not limited to non-public transmission function information provided to marketing function employees, § 358.2(d) is far broader than the Transparency Rule it attempts to summarize.²⁰² National Fuel further asserts that another problem with § 358.2(d) is that, unlike the Standards of Conduct’s other principles, this principle includes specific exceptions, but in so doing implicitly excludes mention of other exceptions contained in the Transparency Rule.²⁰³ National Fuel contends that reference to specific regulatory exceptions in a statement of general principle should be unnecessary and reference to some but not all of the specific regulatory exceptions creates confusion in the regulations.²⁰⁴

103. AGA notes that pipelines are no longer required to post on the Internet within 24 hours each emergency that resulted in a deviation from the Standards, as § 358.4(a)(2) had required pipelines to do prior to Order No. 717.²⁰⁵ However, AGA notes that § 358.7(h) retains the requirement that a transmission provider make available to the Commission upon request the record of certain non-public transmission function information exchanges between transmission function employees and marketing function employees. AGA requests that the Commission clearly define a process by which interested persons may obtain from the Commission the records it receives from pipelines regarding emergency deviations from the Standards, and a process by which interested persons may request that the Commission seek such records for a pipeline.²⁰⁶

104. EEI requests clarification that the “internet Web site” posting requirements can be met by posting information on publicly accessible portions of OASIS.²⁰⁷

105. The Natural Gas Supply Association (NGSA) argues that the Commission erred by removing the discount posting provision from the Standards as proposed in the NOPR.²⁰⁸ Specifically, NGSA contends that the reporting requirement under 18 CFR 284.13(b)(1)(iii) is not sufficient to satisfy the transparency goals of the Standards.²⁰⁹ NGSA remarks that the Commission failed to notice the distinction between the timing of the posting required under 18 CFR 284.13(b)(1)(iii) and that required under the Standards. The former provision requires postings no later than the first nomination under a transaction whereas the Standards would have required a contemporaneous posting had the language been adopted as proposed in the NOPR.²¹⁰ NGSA requests that the Commission adopt the discount posting provisions in the Standards of Conduct as proposed in the NOPR in order to retain the contemporaneous timing of posting.

106. NGSA also argues that the Commission erred by eliminating the requirement of posting tariff waivers for non-affiliates.²¹¹ NGSA argues that the complete elimination of the requirement to post when a pipeline waives its filed tariff in favor of a non-affiliate shields such actions from disclosure, thereby making it impossible for pipeline shippers to determine whether they are being treated comparably and not in an unduly discriminatory manner.²¹² NGSA requests that the Commission require that the waiver posting apply to all waivers granted and not only those granted to an affiliate.²¹³

107. NGSA also contends that the Commission erred by eliminating all posting requirements with respect to exercises of discretion provided for in the pipeline’s tariff.²¹⁴ NGSA argues that the simple fact that certain acts are permitted under a pipeline’s tariff is not sufficient reason to eliminate posting requirements because exercises of discretion can still result in discriminatory behavior.²¹⁵ NGSA notes that discounting rates is an act of

discretion that is nonetheless subject to posting because it allows others to monitor whether they are being treated similarly or not.²¹⁶ NGSA claims that there is no reason for the Commission to treat other acts of discretion any differently.²¹⁷ NGSA asserts that the Commission should adopt a rule of thumb whereby a pipeline would post individual acts of discretion that are not generic in application, which are not available to all shippers and that cannot be denied when requested.²¹⁸

108. NGSA requests that the Commission clarify that (1) a marketing function employee who believes that he may have received non-public transmission function information must notify the transmission provider regardless of how such information was obtained and (2) if the transmission provider determines that the information disclosed to the marketing function employee was, in fact, a violation, it must post the disclosed information.²¹⁹ NGSA states that Order No. 717 eliminates the proposal for transmission providers to post non-public information disclosed to a marketing affiliate by a third party.²²⁰ NGSA contends that the Commission went from proposing to bar marketing function employees from receiving non-public transmission function information from any source, and requiring posting of such information if received, to a final rule that eliminates both of these requirements and requests the clarification as a middle ground.²²¹

109. TAPS contends that the Commission should require transmission providers to identify their marketing function employees by name, job title and description, and position in the chain of command on their websites.²²² TAPS argues that this requirement would facilitate monitoring of compliance with the Independent Functioning Rule and help employees comply with the No Conduit Rule by providing a centralized and authoritative list of the employees to whom employees may not provide non-public transmission function information.²²³

110. EEI requests clarification that transmission providers are not required to post the names of transmission function employees on the Internet.²²⁴

²⁰⁰ *Id.*

²⁰¹ National Fuel at 34.

²⁰² *Id.* at 33–34.

²⁰³ *Id.* at 34.

²⁰⁴ *Id.*

²⁰⁵ AGA at 16.

²⁰⁶ AGA at 15–16.

²⁰⁷ EEI at 13.

²⁰⁸ NGSA Nov. 17, 2008 Request for Clarification or Rehearing at 5.

²⁰⁹ *Id.* at 6.

²¹⁰ *Id.*

²¹¹ *Id.* at 8.

²¹² *Id.* at 9.

²¹³ *Id.*

²¹⁴ *Id.* at 11.

²¹⁵ *Id.* at 12.

²¹⁶ *Id.*

²¹⁷ *Id.*

²¹⁸ *Id.*

²¹⁹ *Id.* at 15.

²²⁰ *Id.*

²²¹ *Id.* at 16.

²²² TAPS at 45.

²²³ *Id.* at 46.

²²⁴ EEI at 18.

EEI states that the regulatory text makes no mention of posting of names, but paragraph 246 of Order No. 717 does make reference to “section 358.7(f)(1) covering the posting of job titles and names of transmission function employees.”²²⁵

111. EEI notes that Order No. 717 retains the concept that an “affiliate” can include a “functional unit” of a transmission provider and that the rules also require that a transmission provider maintain its books of account and records separately from its affiliates that employ or retain marketing function employees.²²⁶ EEI requests clarification that a “functional unit” of a transmission provider that performs marketing functions is not required to keep its books separately from those of the transmission provider.²²⁷

112. National Fuel contends that the language in § 358.7(b) regarding the transaction specific exemption is unduly narrow and should be refined.²²⁸ National Fuel argues that the regulation should encompass communications related to transportation agreements (not merely service requests) and those concerning requests for interconnections and new infrastructure.²²⁹

Commission Determination

113. We grant the clarification requested by MidAmerican to clarify one of the General Principles in § 358.2(d) so that it is consistent with other sections of part 358. Specifically, we clarify that transmission providers may allow their transmission function employees to exchange non-public transmission function information to non-marketing function employees without the need for disclosure. While we do not revive the concept of shared employees, we agree with MidAmerican that the language in § 358.2(d) needs to be clarified so as not to imply that transmission providers would have to provide equal access to non-public transmission function information to all customers following disclosure of non-public transmission function information to non-marketing function employees. For example, if a unit of one transmission provider provides information technology support for other transmission providers in a holding company system, these non-marketing function employees may become privy to non-public transmission function information.

However, we note that these employees remain obligated to abide by the No Conduit Rule. We will revise the language in § 358.2(d) to reflect this clarification.

114. The Commission agrees with INGAA and National Fuel that the “General Principle” in § 358.2(d) does not identify the disclosure exemption for specific requests for transmission service under § 358.7. While we agree with National Fuel that § 358.2(d) applies to non-public information provided to marketing function employees, it was not the Commission’s intention to have the “General Principle” describe all exemptions more fully described in subsequent sections of the Standards of Conduct. However, to alleviate any confusion surrounding the scope of the “General Principle,” we will revise the language in § 358.2(a), § 358.2(b), § 358.2(c), and § 358.2(d) as noted herein.

115. We deny AGA’s request that the Commission define a process by which interested persons may obtain from the Commission the records it receives from pipelines regarding emergency deviations from the Standards, and a process by which interested persons may request that the Commission seek such records for a pipeline. Under § 358.7(h)(1), a transmission provider’s transmission function employees are allowed to exchange certain non-public transmission function information with marketing function employees as necessary to maintain or restore operation of the transmission system and according to the requirements in § 358.7(h)(2) without making a contemporaneous record of the exchange during emergency situations. For these emergency situations, a record must be made as soon as practicable following the emergency and must be made available to the Commission upon request.

116. The Commission has never required the information exchanged under this emergency exception be made publicly available and declines to create such a process here or to create a process for an entity to ask the Commission to exercise its discretion in requesting such records. The Independent Functioning Rule in former § 358.4(a)(2) only required posting of a notice of an emergency, not posting of any information exchanged. As we stated in the NOPR with respect to employee interactions regarding reliability functions, “it [is] the first order of business on the part of a transmission provider to ensure reliability of operations.”²³⁰ We

therefore provided this exception to the Independent Functioning Rule to ensure that an entity can focus on responding to the emergency without concern for contemporaneous recordkeeping.²³¹

117. We grant EEI’s request and provide confirmation for purposes of compliance with the Internet posting requirements under the Standards of Conduct that it is acceptable to post information on a publicly accessible portion of OASIS that can be reached from a transmission provider’s Web site by Internet link. As we noted in Order No. 717, some transmission owners who are members of RTOs or ISOs may not have their own OASIS²³² and this clarification ensures that information will be accessible to all interested entities.

118. The Commission denies NGS’s request to adopt the discount posting provisions in the Standards of Conduct as proposed in the NOPR. Posting no later than the first nomination is consistent with how all other shippers are treated and provides the necessary transparency.

119. We deny NGS’s request to require that the waiver posting requirement apply to all waivers granted and not only those granted to an affiliate. Section 284.13(b)(1)(viii) already requires posting of all instances where a transportation contract deviates from the pipeline’s tariff, and the Standards of Conduct are not intended to be duplicative of the panoply of pipeline-specific posting requirements. Rather, the gravamen of the abuse targeted by the Standards is undue preference to affiliates. And, as Order No. 717 stated, a blanket requirement to post all waivers and exercises of discretion goes beyond what is needed to alert customers and others to possible acts of undue discrimination or preferences in favor of an affiliate.²³³ Furthermore, we note that if a tariff does not permit a particular waiver, a pipeline must come to the Commission to request a waiver, which would provide notice of the request. If the tariff gives the pipeline discretion to waive provisions, then the Commission would have already considered whether notice was necessary for that particular waiver provision after the pipeline first proposed such tariff language. In many cases such tariff provisions require the pipeline to provide some sort of notice. Because NGS has not shown a need for a blanket posting requirement applicable to all tariff waivers granted to

²²⁵ *Id.*

²²⁶ EEI at 17.

²²⁷ EEI at 17.

²²⁸ National Fuel at 36–37.

²²⁹ *Id.*

²³¹ *Id.*

²³² Order No. 717, FERC Stats. & Regs. ¶ 31,280 at P 247.

²³³ *Id.* P 214.

²³⁰ NOPR, FERC Stats. & Regs. ¶ 32,630 at P 33.

non-affiliates, we decline to grant NGSAs's request for rehearing.²³⁴

120. The Commission denies NGSAs's request to adopt a rule of thumb whereby a pipeline would post individual acts of discretion that are not generic in application, which are not available to all shippers and that cannot be denied when requested. As we stated in support of our determination in Order No. 717, an act of discretion occurs when the specific tariff provision involves an exercise of judgment on the part of the transmission provider, *e.g.*, which type of credit is acceptable. When a pipeline submits a specific tariff provision that allows the pipeline to exercise discretion to the Commission for review and approval, the pipeline also serves copies of the filing on its customers. The Commission also provides notice of the filing and the opportunity for comments, as such, the Commission considers customers to have had notice that the pipeline could exercise discretion under that particular tariff provision. Transmission providers exercise their discretion and make judgment calls on an ongoing basis and recording all of these matters would place a substantial administrative burden on them when the customers have already had notice that the pipeline can exercise such discretion for a specific tariff provision.²³⁵ Furthermore, audits would reveal acts of discriminatory discounting.

121. The Commission denies NGSAs's request for clarification that marketing function employees be required to report any disclosure of non-public transmission function information to the transmission provider. The No Conduit Rule will continue to prohibit a transmission provider from using anyone as a conduit for disclosure of non-public transmission function information to a marketing function employee including an employee, contractor, consultant or agent of an affiliate of a transmission provider that is engaged in marketing functions. As we stated in Order No. 717, we eliminated the prohibition in proposed section 358.6(a)(2), which would have prohibited marketing function employees from receiving non-public transmission function information from any source because of the difficulties in determining whether a marketing function employee may have willingly and knowingly or inadvertently

received such information.²³⁶ However, we reiterate, as we said in Order No. 717, that "if a transmission provider uses anyone as a conduit for improper disclosures, such an event would be considered an improper disclosure and should be posted."²³⁷ We also noted in Order No. 717 in discussing Standards of Conduct training that transmission function employees and marketing function employees are the two core categories of employees that should be most cognizant of the rules. Although we deleted the prohibition against marketing function employees receiving transmission function information due to the possibility such receipt could be inadvertent, "it is expected that if someone attempted to pass such information to a marketing function employee, the marketing function employee would not only refuse it but would report the individual to the company's chief compliance officer or other appropriate individual."²³⁸

122. The Commission denies TAPS' request that we require transmission providers to identify their marketing function employees by name, job title and description, and position in the chain of command on their Web sites. Specifically, we find no basis for TAPS' contention that names of marketing function employees and their position in the chain of command are necessary for either monitoring a transmission provider's compliance with the Independent Functioning Rule or facilitating employee compliance with the No Conduit Rule. Based on our past experience, we find that a listing of job title and description is sufficient for Standards of Conduct compliance. Furthermore, any benefit that would result from a listing of names and an explanation of the chain of command would be marginal at best.

123. We grant EEI's clarification request with regard to posting of names of transmission function employees on the Internet. We clarify that transmission providers are not required to post the names of transmission function employees on the Internet. Order No. 717 incorrectly mentioned "names" in explaining the requirement in § 358.7(f)(1) in P 246.

124. We will also grant EEI's request and clarify that a "functional unit" of a transmission provider that performs marketing functions is not required to keep its books separately from those of the transmission provider. However, we note that the No Conduit Rule prohibits a transmission provider from allowing

non-public transmission function information to be disclosed to marketing function employees through a joint set of books and records.

125. The Commission denies National Fuel's request to revise § 358.7(b) to encompass communications related to transportation agreements and those concerning requests for interconnections and new infrastructure. However, we clarify that the transaction specific exemption is not limited to communications concerning requests for transmission service. The transaction specific exemption includes communications related to transportation agreements, specific interconnections and new infrastructure needed for the specific request.

E. Other Definitions—Transmission Function Information

126. EEI seeks clarification that information needed to make economic decisions affecting generation dispatch, such as unit commitment, purchase and sale decisions, should not be classified as non-public transmission function information and is thus not subject to the recordation requirement in 18 CFR 358.7(h).²³⁹ Western Utilities agrees with EEI's contention that information related to generation dispatch should not be considered non-public transmission function information.²⁴⁰ Western Utilities argues that this exception should be expanded to include unit commitment.

127. EEI notes that the regulatory text adopted by Order No. 717 provides that "a transmission provider's transmission function employees and marketing function employees may exchange certain non-public transmission function information * * * in which case the transmission provider must make and retain a contemporaneous record of all such exchanges except in emergency circumstances" and therefore by its terms applies only to exchanges of non-public transmission function information.²⁴¹ EEI further states that the types of information that may be exchanged subject to this recordation process include "[i]nformation necessary to maintain or restore operation of the transmission system or generating units, or that may affect the dispatch of generating units."²⁴² EEI notes that the confusion surrounds whether the new exclusion, and its recordation process, is intended to apply to all information used in

²³⁴ See, *e.g.*, *Norstar Operating LLC v. Columbia Gas Transmission Corp.*, 118 FERC ¶ 61,221, at P 147 (2007) (tariff requires posting of waiver of gas quality provision).

²³⁵ Order No. 717, FERC Stats. & Regs. ¶ 31,280 at P 216.

²³⁶ *Id.* P 200-01.

²³⁷ *Id.* P 236.

²³⁸ *Id.* P 306.

²³⁹ EEI at 1-2.

²⁴⁰ Western Utilities at 12. See also EEI at 6.

²⁴¹ EEI at 5 (citing 18 CFR 358.7(h)(1)).

²⁴² *Id.* (citing 18 CFR 358.7(h)(2)).

generation dispatch.²⁴³ EEI requests clarification concerning whether information about a company's own generation and load, such as the type of information discussed in *Indianapolis Power & Light Co.*, 90 FERC ¶ 61,174 at 61, 575–76 and *Indianapolis Power & Light Co.*, 92 FERC ¶ 61,002 at 61,003, may be provided to marketing function employees without being subject to the recordation requirement.²⁴⁴

128. EEI also requests clarification that the other categories of information identified in § 358.7(h)(2)—*i.e.*, information pertaining to compliance with Reliability Standards and information necessary to maintain or restore operation of the transmission system or generating units—are not *per se* deemed transmission function information subject to the recordation requirement.²⁴⁵ Western Utilities also requests clarification of this subsection, arguing that § 358.7(h)(2)(i) creates two types of information subject to the exclusion, information pertaining to compliance with Reliability Standards as well as information necessary to maintain or restore operations.²⁴⁶ Similarly, MidAmerican requests that the Commission clarify that not all information involving reliability and generation dispatch is non-public transmission function information.²⁴⁷ For example, MidAmerican notes that while unit economics or rail outage may affect the dispatch of generating units, this type of information does not fall within the scope of non-public transmission function information.²⁴⁸

129. EEI also requests further specificity on the content required for records for purposes of ensuring compliance with the recordation requirement.²⁴⁹ EEI believes that a record of the names of employees participating, the date, time, duration, and subject matters discussed should be sufficient and asks the Commission to confirm this interpretation.²⁵⁰

130. EEI requests clarification regarding the treatment of information that is not close in time to current day-to-day transmission operations.²⁵¹ Specifically, EEI requests clarification as to (i) whether information that was transmission function information in real-time is no longer transmission function information when the events in question have passed, and if so, how

much time should pass before information is no longer regarded as transmission function information, and (ii) whether information about future occurrences, such as a transmission outage planned thirteen months in the future, is transmission function information, and again, where the line is drawn.²⁵²

Commission Determination

131. We clarify for EEI that certain types of information about a company's own generation, load, and generation dispatch are not subject to the recordation requirement in § 358.7(h). Section 358.3(j) defines “transmission function information” as “information relating to transmission functions.” Section 358.3(h) defines “transmission function” as “the planning, directing, organizing, or carrying out of day-to-day transmission operations, including the granting and denying of transmission service requests.” To the extent that information concerning a company's own generation, load, and generation dispatch is not “transmission function information” as defined in § 358.3(j), then this information may be provided to marketing function employees without being subject to the recordation requirement.

132. We grant EEI's clarification request and clarify that the other categories of information identified in § 358.7(h)(2) are not *per se* transmission function information subject to the recordation requirement, but could be if the information falls within the definition of transmission function information in § 358.3. In response to EEI and Western Utilities, we also clarify that information related to unit commitment is not “non-public transmission function information” *per se*. However, should transmission function employees inadvertently provide “non-public transmission function information” to the marketing function employees, as transmission function employees work with marketing function employees to develop the unit commitment and dispatch plan, we remind transmission providers that § 358.7(h) would require recordation of this inadvertent disclosure.

133. In response to Western Utilities' request regarding information subject to the exclusion in § 358.7(h)(2), we clarify that the “and” is intended to mean that there are two types of information subject to the exclusion. The regulatory text in § 358.7(h)(2) is simply a list.

134. We grant EEI's request for more specificity on the content required for

records for purposes of ensuring compliance with the recordation requirement. We agree that names, date, time, duration, and subject matter are sufficient content for purposes of the records. When recording the subject matter, transmission providers should record details that are clear enough to allow the Commission to determine what non-public information was exchanged and why this exchange of information was necessary.

135. We grant EEI's clarification request in part and deny it in part regarding the treatment of information that is not close in time to current day-to-day transmission operations, whether the events are past or future. Given the differences in how various entities operate, we decline to create a general rule regarding the staleness of non-public transmission function information. Individual waivers may be sought from the Commission for those instances in which an entity desires to share non-public transmission function information otherwise prohibited by the Standards of Conduct. However, we clarify that information about a planned transmission outage is always transmission function information no matter how far in the future the planned transmission outage will occur.

136. The Commission clarifies that not all generation dispatch and reliability information is non-public transmission function information. MidAmerican states that unit economics or rail outage may affect the dispatch of generating units, but that this type of information does not fall within the scope of non-public transmission function information. We agree with its statement and so clarify.

F. Training Requirements

137. EEI states that if read literally, the training requirements could suggest that all supervisory employees within the company require training. EEI requests clarification as to whether the training requirements apply to all supervisory employees within the company or just those supervisors who are likely to become privy to transmission function information themselves or who supervise the other employees subject to the Standards.²⁵³

138. MidAmerican believes that the requirements in § 358.8(b)(2) are adequate to ensure that employees with the greatest potential to provide undue preference to marketing function personnel have received information and training on the Standards. MidAmerican argues that § 358.8(b)(1) is unnecessary and inconsistent with

²⁴³ *Id.* at 5.

²⁴⁴ *Id.* at 6.

²⁴⁵ *Id.*

²⁴⁶ Western Utilities at 8.

²⁴⁷ MidAmerican at 16.

²⁴⁸ MidAmerican at 16–17.

²⁴⁹ EEI at 6.

²⁵⁰ *Id.*

²⁵¹ *Id.* at 16.

²⁵² *Id.*

²⁵³ EEI at 16.

§ 358.8(2).²⁵⁴ MidAmerican states that by using the term “affiliates” in § 358.8(b)(1), the Commission appears to be requiring transmission providers to somehow provide Standards information to all of their affiliates’ employees, including, potentially, non-energy companies, foreign companies and companies that would not have any understanding of the Commission.²⁵⁵ MidAmerican also argues that this obligation is inconsistent with § 358.8(b)(2), which limits the distribution of written procedures to transmission provider employees likely to become privy to transmission function information.²⁵⁶

139. Western Utilities claims that the Commission’s explanation of how often employees must be trained conflicts with § 358.8(c)(1). In Order No. 717, the Commission stated the following:

Furthermore, it is not necessary for the transmission provider to track annual dates for each employee; if the transmission provider prefers, it may train all its employees, or all its employees in a given category, at a certain time each year. New employees, after their initial training, can be fit within this schedule. However, *the employee should not go longer than a year without participating in training.*²⁵⁷

However, § 358.8(c)(1) provides that a transmission provider “must provide annual training.” Western Utilities requests that the Commission clarify that “a year” refers to a calendar year, not 365 days.²⁵⁸ Western Utilities contends that if training must occur every 365 days, each new employee will need to be on an individual schedule rather than simply fitting into the company’s regular training schedule.

Commission Determination

140. The Commission grants clarification regarding which supervisory employees are subject to the training requirements. In Order No. 717, we stated that there is a clear need for officers, directors, and supervisory employees to have an understanding of the Standards since they will “be in a position to interact with both transmission function employees and marketing function employees, or be responsible for responding to any questions or concerns about the Standards from the employees who report to them.”²⁵⁹ We clarify in response to EEI that the training

requirement applies to supervisory employees who supervise other employees subject to the Standards or who may come in contact with non-public transmission function information.

141. The Commission disagrees with MidAmerican that § 358.8(b)(1) is unnecessary and inconsistent with § 358.8(b)(2) and denies its request to delete § 358.8(b)(1). Section 358.8(b)(1) is a general requirement that a transmission provider have measures in place to ensure that the Independent Functioning Rule and the No Conduit Rule are observed by its employees and those of its affiliates. While the number of employees subject to the Independent Functioning Rule may be smaller, the No Conduit Rule prohibits a transmission provider from using anyone as a conduit. Therefore, a transmission provider must have measures in place to ensure that these requirements are followed. It is up to the transmission provider to design and implement those measures. However, in § 358.8(b)(2) we specifically require that transmission providers distribute written procedures to those employees likely to become privy to transmission function information.

142. We clarify in response to Western Utilities that we intended “a year” to mean a calendar year and not “365 days” in our explanation of how often employees must be trained in Order No. 717.

G. Miscellaneous Matters

143. EEI notes that § 358.2(d) uses the term “transmission function customers” and recommends that this undefined term be changed to “transmission customers.”²⁶⁰

144. EEI requests clarification that the NAESB requirements that have been rendered obsolete by Order No. 717 may be disregarded.²⁶¹ Specifically, EEI refers to Business Practices for OASIS Standards and Communication Protocols (WEQ-002), which provides requirements for posting on OASIS links to information that was required by the pre-Order No. 717 Standards, but is no longer required, such as organizational charts.²⁶²

145. EPSA requests clarification on whether generators scheduling transmission through an RTO or ISO must adhere to the posting requirements of the Independent Functioning Rule under § 358.1.²⁶³ EPSA asserts that the waiver found in § 358.1(c) of the

Commission’s regulations applies, on its face, only to wholesale transmission providers.²⁶⁴ EPSA states that while transmission providers may file for a waiver of the Standards of Conduct if they belong to a Commission-approved ISO or RTO, it is not clear whether an affiliated wholesale generator would still be subject to the posting requirements of the Independent Functioning Rule if it is scheduled through an RTO.²⁶⁵

146. Southwest Gas contends that the phrase “by a local distribution company” contained within § 358.3(c)(2)(v) does not reflect clearly the fact that the exemption from marketing function includes those LDCs that operate across state lines under NGA section 7(f).²⁶⁶ Southwest Gas argues that while these companies are natural gas companies under the NGA, they function as LDCs and there is no evidence of affiliate abuse by NGA section 7(f) companies.²⁶⁷ Southwest Gas requests revision of the regulatory text of § 358.3(c)(2)(v) to include NGA section 7(f) companies.

Commission Determination

147. We grant the clarification request by EEI in regards to changing the term “transmission function customers” in § 358.2(d) and change the term to “transmission customers.”

148. We grant the clarification request of EEI regarding compliance with the NAESB Business Practice Standards to note that, as stated in a NOPR issued earlier this year,²⁶⁸ the Commission will not require public utilities to comply with the NAESB Business Practice Standards incorporated by reference by the Commission that require information to be posted in a manner inconsistent with Order No. 717 until such time as the Commission issues a new standard conforming to the changes in Order No. 717. While the NOPR made this determination for the requirements of WEQ-001-13.1.2, version 1.5, we note that the same is true for all aspects of the NAESB Business Practice Standards that are inconsistent with Order No. 717’s posting requirements. We understand that NAESB is working on making appropriate revisions.

149. We deny EPSA’s request for clarification concerning whether a wholesale generator scheduling transportation transactions with an RTO is obligated by the posting requirements

²⁵⁴ MidAmerican at 13–14.

²⁵⁵ *Id.* at 13.

²⁵⁶ *Id.*

²⁵⁷ Order No. 717, FERC Stats. & Regs. ¶ 31,280 at P 309 (emphasis added).

²⁵⁸ Western Utilities at 14.

²⁵⁹ Order No. 717, FERC Stats. & Regs. ¶ 31,280 at P 307.

²⁶⁰ EEI at 18.

²⁶¹ *Id.* at 17.

²⁶² *Id.*

²⁶³ EPSA at 1–2.

²⁶⁴ *Id.* at 2.

²⁶⁵ *Id.*

²⁶⁶ Southwest Gas at 12.

²⁶⁷ *Id.*

²⁶⁸ *Standards for Business Practices and Communication Protocols for Public Utilities*, FERC Stats. & Regs. ¶ 32,640, at P 16 (2009).

of the Independent Functioning Rule. We note that the Independent Functioning Rule in § 358.5 no longer contains posting requirements. For this reason, we find that EPSA's request for clarification has been rendered moot.

150. The Commission grants the clarification request by Southwest Gas to include NGA section 7(f) companies within the LDC exemption, and will revise the regulatory text of § 358.3(c)(2)(v) to read, "On-system sales by an intrastate natural gas pipeline, by a Hinshaw interstate pipeline exempt from the Natural Gas Act, by a local distribution company, or by a local distribution company operating under section 7(f) of the Natural Gas Act."²⁶⁹ While section 7(f) companies are natural gas companies under the NGA, they function as LDCs and should be treated the same as LDCs for purposes of the LDC exemption under the Standards of Conduct.

IV. Document Availability

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

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

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

V. Effective Date

154. Changes to Order No. 717 adopted in this order on rehearing and clarification are effective November 23, 2009.

²⁶⁹ The change to the regulatory language moving "on-system sale" to the beginning of section 358.3(c)(2)(v) is discussed *supra*.

List of Subjects in 18 CFR Part 358

Electric power plants, Electric utilities, Natural gas, Reporting and recordkeeping requirements.

By the Commission.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

■ In consideration of the foregoing, the Commission amends Part 358, Chapter I, Title 18, *Code of Federal Regulations*, as follows.

PART 358—STANDARDS OF CONDUCT

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

Authority: 15 U.S.C. 717-717w, 3301-3432; 16 U.S.C. 791-825r, 2601-2645; 31 U.S.C. 9701; 42 U.S.C. 7101-7352.

■ 2. Section 358.2 is revised to read as follows:

§ 358.2 General principles.

(a) As more fully described and implemented in subsequent sections of this part, a transmission provider must treat all transmission customers, affiliated and non-affiliated, on a not unduly discriminatory basis, and must not make or grant any undue preference or advantage to any person or subject any person to any undue prejudice or disadvantage with respect to any transportation of natural gas or transmission of electric energy in interstate commerce, or with respect to the wholesale sale of natural gas or of electric energy in interstate commerce.

(b) As more fully described and implemented in subsequent sections of this part, a transmission provider's transmission function employees must function independently from its marketing function employees, except as permitted in this part or otherwise permitted by Commission order.

(c) As more fully described and implemented in subsequent sections of this part, a transmission provider and its employees, contractors, consultants and agents are prohibited from disclosing, or using a conduit to disclose, non-public transmission function information to the transmission provider's marketing function employees.

(d) As more fully described and implemented in subsequent sections of this part, a transmission provider must provide equal access to non-public transmission function information disclosed to marketing function employees to all its transmission customers, affiliated and non-affiliated, except as permitted in this part or otherwise permitted by Commission order.

■ 3. In § 358.3, paragraph (c)(2)(v) is revised to read as follows:

§ 358.3 Definitions.

* * * * *

(c) * * *

(2) * * *

(v) On-system sales by an intrastate natural gas pipeline, by a Hinshaw interstate pipeline exempt from the Natural Gas Act, by a local distribution company, or by a local distribution company operating under section 7(f) of the Natural Gas Act.

* * * * *

[FR Doc. E9-25252 Filed 10-21-09; 8:45 am]

BILLING CODE 6717-01-P

SOCIAL SECURITY ADMINISTRATION

20 CFR Part 404

[Docket No. SSA-2007-0066]

RIN 0960-AG57

Revised Medical Criteria for Evaluating Malignant Neoplastic Diseases

AGENCY: Social Security Administration.

ACTION: Final rule; correction.

SUMMARY: This document corrects the preamble to a final rule published in the **Federal Register** on October 6, 2009, regarding a revision of a medical listing for malignant neoplastic diseases. In that preamble, we cited an incorrect date of publication for the Notice of Proposed Rule Making (NPRM) that had preceded the final rule.

DATES: Effective November 5, 2009.

FOR FURTHER INFORMATION CONTACT: Mark Kuhn, 410-965-1020.

SUPPLEMENTARY INFORMATION:

Correction

In the preamble to the final rule published October 6, 2009 (74 FR 51229) we stated the NPRM (73 FR 22871) was published on April 24, 2008. The NPRM was actually published on April 28, 2008.

In FR Doc. E9-23896 appearing on page 51229 in the **Federal Register** of Tuesday, October 6, 2009, make the following correction in the **SUPPLEMENTARY INFORMATION** section. On page 51229, in the third column, in the fifth line of the first paragraph under Background, change "April 24, 2008" to "April 28, 2008."

Dated: October 16, 2009.

Dean Landis,

Associate Commissioner for Regulations, Social Security Administration.

[FR Doc. E9-25424 Filed 10-21-09; 8:45 am]

BILLING CODE 4191-02-P

DEPARTMENT OF HOMELAND SECURITY**Coast Guard****33 CFR Part 165**

[Docket No. USCG-2009-0870]

RIN 1625-AA00

Safety Zone; Waters Surrounding M/V Guilio Verne and Barge Hagar for the Transbay Cable Laying Project, San Francisco Bay, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary moving safety zone in the navigable waters of San Francisco Bay surrounding the Motor Vessel (M/V) Guilio Verne and barge Hagar while engaged in cable laying operations. Unauthorized persons or vessels are prohibited from entering into, transiting through, or remaining in the safety zone without permission of the Captain of the Port or his designated representative. This safety zone is necessary to protect persons and property from hazards associated with the cable laying operations.

DATES: This temporary final rule is effective from 12 a.m. on October 22, 2009, until 11:59 p.m. on December 1, 2009. This temporary final rule is enforceable with actual notice by Coast Guard personnel beginning October 7, 2009.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG-2009-0870 and are available online by going to <http://www.regulations.gov>, inserting USCG-2009-0870 in the "Keyword" box, and then clicking "Search." They are also available for inspection or copying at the Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call Lieutenant Junior Grade Simone Mausz, U.S. Coast Guard Sector San Francisco, at (415) 399-7443 or e-mail at simone.mausz@uscg.mil. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:**Regulatory Information**

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because the event would occur before the rulemaking process would be completed. The safety zone is necessary to protect the safety of persons and property in the area from the dangers posed by the offloading of heavy equipment. Delaying the effective date of the safety zone would expose members of the public to those dangers, and would be contrary to the public interest.

For the same reasons, the Coast Guard also finds under 5 U.S.C. 553(d)(3) that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Any delay in the effective date of this rule would expose members of the public to the dangers associated with offloading heavy equipment.

Background and Purpose

The Transbay Cable Laying project is necessary to deliver electrical current from a decommissioned power plant in Pittsburg, CA to a power plant in San Francisco to provide the city with energy. This rule is necessary for the safety of the public and vessels transiting to other berths during the offload of this cargo. This rule prohibits entry of any vessel or person into the safety zone without specific authorization from the Captain of the Port or his designated representative.

Discussion of Rule

This temporary moving safety zone will remain in effect from 12 a.m. October 7, 2009 through 11:59 p.m. December 1, 2009 and includes all waters extending from the surface area to the sea floor within 1,000 feet of the vessel and barge.

The effect of the temporary moving safety zone will be to restrict navigation in the vicinity of the cable laying operations while the cable is being deployed and buried. Except for persons or vessels authorized by the Coast Guard Patrol Commander, no person or vessel

may enter or remain in the restricted area. These regulations are needed to keep spectators and vessels a safe distance away from the vessel to ensure the safety of participants, spectators, and transiting vessels.

Regulatory Analyses

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

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.

Although this rule restricts access to the waters encompassed by the temporary moving safety zone, the effect of this rule will not be significant because vessels will be able to safely transit around the area and the local waterway users will be notified via public Broadcast Notice to Mariners to ensure the temporary moving safety zone will result in minimum impact. The entities most likely to be affected are pleasure craft engaged in recreational activities.

Small Entities

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

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

This rule may affect owners and operators of pleasure craft engaged in recreational activities and sightseeing. This rule will not have a significant economic impact on a substantial number of small entities for several reasons: (i) Vessel traffic can pass safely around the area; (ii) vessels engaged in recreational activities and sightseeing have ample space outside of the effected portion of the San Francisco Bay to engage in these activities; (iii) this rule will encompass only a small portion of

the waterway for a limited period of time; and, (iv) the maritime public will be advised in advance of this safety zone via Broadcast Notice to Mariners.

Assistance for Small Entities

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

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

Collection of Information

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

Federalism

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

Unfunded Mandates Reform Act

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

Taking of Private Property

This rule will not affect a taking of private property or otherwise have taking implications under Executive

Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

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

Protection of Children

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

Indian Tribal Governments

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

Energy Effects

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

Technical Standards

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

systems practices) that are developed or adopted by voluntary consensus standards bodies.

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

Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023.1 and Commandant Instruction M16475.ID, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321-4370f), and have concluded this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded, under figure 2-1, paragraph (34)(g), of the Instruction because the rule involves establishing a safety zone. An environmental analysis checklist and a categorical exclusion determination are available in the docket where indicated under

ADDRESSES.

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05-1(g), 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. Add temporary § 165-T11-243 to read as follows:

§ 165-T11-243 Safety Zone; Transbay Cable Laying Project, San Francisco Bay, CA.

(a) *Location.* The following area is a temporary moving safety zone: All waters of San Francisco Bay up to Pittsburg, CA, from surface to bottom, within 1,000 feet of the M/V Guilio Verne and the barge Hagar.

(b) *Definitions.* As used in this section, *designated representative* means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, or local officer

designated by or assisting the Captain of the Port San Francisco (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) Under the general regulations in § 165.23, entry into, transiting, or anchoring within this safety zone is prohibited unless authorized by the COTP or the COTP's designated representative.

(2) The safety zone is closed to all vessel traffic, except as may be permitted by the COTP or the COTP's designated representative.

(3) Vessel operators desiring to enter or operate within the safety zone must contact the COTP or the COTP's designated representative to obtain permission to do so. Vessel operators given permission to enter or operate in the temporary moving safety zone must comply with all directions given to them by the COTP or the COTP's designated representative. Persons and vessels may request permission to enter the safety zone on VHF-16 or through the 24-hour Command Center at telephone (415) 399-3547.

(d) *Effective period.* This section is effective from 12 a.m. on October 7, 2009 through 11:59 p.m. on December 1, 2009.

Dated: October 6, 2009.

P.M. Gugg,

Captain, U.S. Coast Guard, Captain of the Port San Francisco.

[FR Doc. E9-25393 Filed 10-21-09; 8:45 am]

BILLING CODE 4910-15-P

POSTAL SERVICE

39 CFR Part 20

Nonmailable Items Prohibited in All Outbound International Mail—Update

AGENCY: Postal Service™.

ACTION: Final rule.

SUMMARY: The Postal Service is revising and adding new standards which codify that replica and inert explosive devices, and counterfeit and pirated items are nonmailable in outbound international mail.

DATES: *Effective Date:* January 4, 2010.

FOR FURTHER INFORMATION CONTACT: Rick Klutts, 813-877-0372.

SUPPLEMENTARY INFORMATION: Consistent with Proposals 20.15.2 and 20.15.6—adopted by the 24th Congress of the Universal Postal Union (UPU) in Geneva Switzerland on July 23–August 12, 2008,—that amend Article 15 of the UPU Convention, we are revising *Mailing Standards of the United States Postal Service, International Mail Manual (IMM®)* to make replica and

inert explosive devices and counterfeit and pirated items nonmailable.

Replica and Inert Explosive Devices

Consistent with Proposal 20.15.2, this prohibition is intended to apply to devices that were originally designed for military or combat use (including training) and is also extended to replicas of such items. Specific items include replica and inert explosive devices and military ordnance, such as grenades, ammunition, shells and the like.

This prohibition does not extend to items such as children's toys or articles that do not represent such items in a realistic manner.

Counterfeit or Pirated Articles

Consistent with UPU Proposal 20.15.6, this prohibition is intended to reduce the circulation of counterfeit and pirated articles between UPU members. The prohibition also illustrates that the UPU's members actively support the World Customs Organization's current campaign to thwart production and circulation of counterfeited and pirated products, such as dangerous toys and electrical items, dangerous counterfeit medicines and counterfeit branded goods, which do economic harm to domestic and international companies.

List of Subjects in 39 CFR Part 20

Foreign relations, International postal services.

■ Accordingly, 39 CFR part 20 is amended as follows:

PART 20—[AMENDED]

■ 1. The authority citation for 39 CFR part 20 is revised to read as follows:

Authority: 5 U.S.C. 552(a); 13 U.S.C. 301-307; 39 U.S.C. 101, 401, 403, 404, 407, 408, 414, 416, 3001-3011, 3201-3219, 3403-3406, 3621, 3622, 3626, 3632, 3633, and 5001.

■ 2. Revise the following sections of *Mailing Standards of the United States Postal Service, International Mail Manual (IMM)* as follows:

Mailing Standards of the United States Postal Service, International Mail Manual (IMM)

1 International Mail Services

* * * * *

130 Mailability International Mail Services

* * * * *

[Revise 136 in its entirety as follows:]

* * * * *

136 Nonmailable Goods

136.1 Dangerous Goods

The following dangerous goods (hazardous materials, as defined in DMM 601) are prohibited in outbound international mail:

- a. Explosives or explosive devices.
- b. Flammable materials.
 - 1. Pyrophoric, flammable, or combustible liquids with a closed cup flash point below 200 °F.
 - 2. Flammable solids, including matches.
- c. Oxidizers.
- d. Corrosives, liquid or solid.
- e. Compressed gases.
 - 1. Flammable.
 - 2. Nonflammable with an absolute pressure exceeding 40 psi at 70 °F or 104 psi at 130 °F.
- f. Poisons, irritants, controlled substances, and drug paraphernalia.
- g. Magnetized material with a magnetic field strength of .002 gauss or more at a distance of 7 feet.
- h. Dry ice (carbon dioxide solid).

136.2 Replica and Inert Explosive Devices

The following types of replica or inert explosive devices are prohibited in outbound international mail:

- 1. Military ordnance, ammunition, and shells.
- 2. Grenades.
- 3. Similar devices that were originally designed for military or combat use (including training).

This prohibition does not extend to items such as children's toys or articles that do not represent such items in a realistic manner.

136.3 Counterfeit and Pirated Items

Any type of counterfeit or pirated article is prohibited in outbound international mail.

* * * * *

Neva R. Watson,

Attorney, Legislative.

[FR Doc. E9-25363 Filed 10-21-09; 8:45 am]

BILLING CODE 7710-12-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R03-OAR-2009-0599; FRL-8971-4]

Approval and Promulgation of Air Quality Implementation Plans; Virginia; Revision to Clean Air Interstate Rule Sulfur Dioxide Trading Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action to approve a revision to the Commonwealth of Virginia State Implementation Plan (SIP). The revision pertains to the timing for the first phase of the sulfur dioxide (SO₂) trading budget under the Commonwealth's approved regulations that implement the requirements of the Clean Air Interstate Rule (CAIR). EPA is approving this revision to change the start date of Virginia's CAIR SO₂ trading budget from the control period in 2009 to the control period in 2010 in accordance with the requirements of the Clean Air Act (CAA).

DATES: This rule is effective on December 21, 2009 without further notice, unless EPA receives adverse written comment by November 23, 2009. If EPA receives such comments, it will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA-R03-OAR-2009-0599 by one of the following methods:

A. <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

B. *E-mail:*
Fernandez.cristina@epa.gov.

C. *Mail:* EPA-R03-OAR-2009-0599, Cristina Fernandez, Chief, Air Quality Planning Branch, Mailcode 3AP21, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. *Hand Delivery:* At the previously-listed EPA Region III address. 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-R03-OAR-2009-0599. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through <http://www.regulations.gov> or e-mail. The <http://www.regulations.gov> Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you

provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through <http://www.regulations.gov>, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the <http://www.regulations.gov> index. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in <http://www.regulations.gov> or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the Virginia Department of Environmental Quality, 629 East Main Street, Richmond, Virginia 23219.

FOR FURTHER INFORMATION CONTACT: Marilyn Powers, (215) 814-2308, or by e-mail at powers.marilyn@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On January 14, 2009, the Commonwealth of Virginia submitted a formal revision to its SIP. The SIP revision consists of a change in timing for the first phase of the Commonwealth's approved CAIR SO₂ trading budget. The start for the first phase of the SO₂ trading budget is changed from the control period in 2009 to the control period in 2010.

II. Summary of SIP Revision

Virginia regulation 9 VAC 5-140-3400 is amended to change the timing for the CAIR SO₂ budget from the control period in 2009 to the control period in 2010. In addition, the section title of 9 VAC 5-140-3400 is changed to specifically reflect the CAIR SO₂ annual trading budgets.

The EPA-administered CAIR SO₂ trading programs under States' CAIR SIPs and under the CAIR FIP start on January 1, 2010, and the associated CAIR SO₂ trading budgets apply starting with the 2010 control period. Virginia's existing provision, requiring an SO₂ budget starting in the 2009 control period, is inconsistent with the CAIR trading program. In the SIP revision, Virginia explains that this change corrects a technical error in its approved CAIR SIP.

III. General Information Pertaining to SIP Submittals From the Commonwealth of Virginia

In 1995, Virginia adopted legislation that provides, subject to certain conditions, for an environmental assessment (audit) "privilege" for voluntary compliance evaluations performed by a regulated entity. The legislation further addresses the relative burden of proof for parties either asserting the privilege or seeking disclosure of documents for which the privilege is claimed. Virginia's legislation also provides, subject to certain conditions, for a penalty waiver for violations of environmental laws when a regulated entity discovers such violations pursuant to a voluntary compliance evaluation and voluntarily discloses such violations to the Commonwealth and takes prompt and appropriate measures to remedy the violations. Virginia's Voluntary Environmental Assessment Privilege Law, Va. Code Sec. 10.1-1198, provides a privilege that protects from disclosure documents and information about the content of those documents that are the product of a voluntary environmental assessment. The Privilege Law does not extend to documents or information (1) that are generated or developed before the commencement of a voluntary environmental assessment; (2) that are prepared independently of the assessment process; (3) that demonstrate a clear, imminent and substantial danger to the public health or environment; or (4) that are required by law.

On January 12, 1998, the Commonwealth of Virginia Office of the Attorney General provided a legal opinion that states that the Privilege Law, Va. Code Sec. 10.1-1198, precludes granting a privilege to documents and information "required by law," including documents and information "required by Federal law to maintain program delegation, authorization or approval," since Virginia must "enforce Federally authorized environmental programs in a manner that is no less stringent than

their Federal counterparts * * *.” The opinion concludes that “[r]egarding § 10.1–1198, therefore, documents or other information needed for civil or criminal enforcement under one of these programs could not be privileged because such documents and information are essential to pursuing enforcement in a manner required by Federal law to maintain program delegation, authorization or approval.”

Virginia’s Immunity law, Va. Code Sec. 10.1–1199, provides that “[t]o the extent consistent with requirements imposed by Federal law,” any person making a voluntary disclosure of information to a state agency regarding a violation of an environmental statute, regulation, permit, or administrative order is granted immunity from administrative or civil penalty. The Attorney General’s January 12, 1998 opinion states that the quoted language renders this statute inapplicable to enforcement of any Federally authorized programs, since “no immunity could be afforded from administrative, civil, or criminal penalties because granting such immunity would not be consistent with Federal law, which is one of the criteria for immunity.”

Therefore, EPA has determined that Virginia’s Privilege and Immunity statutes will not preclude the Commonwealth from enforcing its program consistent with the Federal requirements. In any event, because EPA has also determined that a state audit privilege and immunity law can affect only state enforcement and cannot have any impact on Federal enforcement authorities, EPA may at any time invoke its authority under the CAA, including, for example, sections 113, 167, 205, 211 or 213, to enforce the requirements or prohibitions of the state plan, independently of any state enforcement effort. In addition, citizen enforcement under section 304 of the CAA is likewise unaffected by this, or any, state audit privilege or immunity law.

IV. Final Action

EPA is approving the SIP revision submitted by the Commonwealth of Virginia on January 14, 2009. The SIP revision incorporates timing changes to the Commonwealth’s CAIR SO₂ trading program that make it consistent with the regional CAIR SO₂ trading program, under which SO₂ trading budgets apply starting in 2010.

EPA is publishing this rule without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comment. However, in the “Proposed Rules” section of today’s **Federal**

Register, EPA is publishing a separate document that will serve as the proposal to approve the SIP revision if adverse comments are filed. This rule will be effective on December 21, 2009 without further notice unless EPA receives adverse comment by November 23, 2009. If EPA receives adverse comment, EPA will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. EPA will address all public comments in a subsequent final rule based on the proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting must do so at this time.

V. Statutory and Executive Order Reviews

A. General Requirements

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

- Is not a “significant regulatory action” subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National

Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and

- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

B. Submission to Congress and the Comptroller General

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

C. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by December 21, 2009. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the proposed rules section of today’s **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the

comment in the proposed rulemaking. This action to approve a Virginia SIP revision that changes the applicable start date for its SO₂ trading budget may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Sulfur oxides.

Dated: October 13, 2009.
James W. Newsom,
Acting Regional Administrator, Region III.

■ 40 CFR Part 52 is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for 40 CFR part 52 continues to read as follows:

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

Subpart VV—Virginia

■ 2. In § 52.2420, the table in paragraph (c) is amended by revising the entry for Chapter 140, Section 5–140–3400 to read as follows:

§ 52.2420 Identification of plan.

* * * * *
 (c) * * *

EPA-APPROVED VIRGINIA REGULATIONS AND STATUTES

State citation	Title/subject	State effective date	EPA approval date	Explanation [former SIP citation]
*	*	*	*	*
9 VAC 5, Chapter 140 Regulations for Emissions Trading Programs				
*	*	*	*	*
Part IV SO₂ Annual Trading Program				
5–140–3400	State trading budgets	12/12/07	10/22/09 [Insert page number where the document begins].	1. In section title, replace “State” with “CAIR SO ₂ Annual.” 2. In paragraph 1, replace 2009 with 2010.
*	*	*	*	*

[FR Doc. E9–25355 Filed 10–21–09; 8:45 am]
BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 09–2181; MB Docket No. 09–159; RM–11557]

Television Broadcasting Services; St. Petersburg, FL

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission grants a petition for rulemaking filed by Bay Television, Inc., the licensee of station WTTA(TV), channel 38, St. Petersburg, Florida, requesting the substitution of channel 32 for its assigned channel 38 at St. Petersburg.

DATES: This rule is effective October 22, 2009.

FOR FURTHER INFORMATION CONTACT: Adrienne Y. Denysyk, Media Bureau, (202) 418–1600.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission’s *Report and Order*, MB Docket No. 09–159, adopted October 1, 2009, and released October 7, 2009. The full text of this document is available for public inspection and copying during normal business hours in the FCC’s Reference Information Center at Portals II, CY–A257, 445 12th Street, SW., Washington, DC 20554. This document will also be available via ECFS (<http://www.fcc.gov/cgb/ecfs/>). (Documents will be available electronically in ASCII, Word 97, and/or Adobe Acrobat.) This document may be purchased from the Commission’s duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone 1–800–478–3160 or via e-mail <http://www.BCPIWEB.com>. To request this document in accessible formats (computer diskettes, large print, audio recording, and Braille), send an e-mail to fcc504@fcc.gov or call the Commission’s Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY). This document does not contain information collection requirements

subject to the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, therefore, it does not contain any information collection burden “for small business concerns with fewer than 25 employees,” pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4). Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

The Commission will send a copy of this *Report and Order* in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

List of Subjects in 47 CFR Part 73

Television, Television broadcasting.

■ For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334, 336.

§ 73.622 [Amended]

■ 2. Section 73.622(i), the Post-Transition Table of DTV Allotments under Florida, is amended by adding channel 32 and removing channel 38 at St. Petersburg.

Federal Communications Commission.

Clay C. Pendarvis,

Associate Chief, Video Division, Media Bureau.

[FR Doc. E9-25231 Filed 10-21-09; 8:45 am]

BILLING CODE 6712-01-P

DEPARTMENT OF TRANSPORTATION**Pipeline and Hazardous Materials Safety Administration****49 CFR Parts 172 and 174**

[RSPA Docket No. 2006-26322 (HM-206F)]

RIN 2137-AE21

Hazardous Materials: Revision of Requirements for Emergency Response Telephone Numbers*Correction*

In rule document E9-24799 beginning on page 53413 in the issue of Monday, October 19, 2009, make the following correction:

On page 53413, in the third column, under the **DATES** section, in the second line, "November 18, 2009" should read "October 1, 2010".

[FR Doc. Z9-24799 Filed 10-21-09; 8:45 am]

BILLING CODE 1505-01-D

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration****50 CFR Part 622**

[Docket No. 070718369-8731-02]

RIN 0648-XS50

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Reef Fish Fishery of the Gulf of Mexico; Closure of the 2009 Gulf of Mexico Recreational Fishery for Greater Amberjack

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS closes the recreational fishery for greater amberjack in the exclusive economic zone (EEZ) of the Gulf of Mexico (Gulf). During the closure, the bag and possession limit for

greater amberjack in or from the Gulf EEZ is zero. In addition, a person aboard a vessel for which a Federal charter vessel/headboat permit for Gulf reef fish has been issued must also abide by these closure provisions in state waters. NMFS has determined this action is necessary to prevent the recreational fishery for greater amberjack from exceeding its quota for the fishing year. This closure is necessary to prevent overfishing of Gulf greater amberjack.

DATES: The closure is effective 12:01 a.m., local time, October 24, 2009, through December 31, 2009.

FOR FURTHER INFORMATION CONTACT: Dr. Steve Branstetter, telephone 727-551-5796, fax 727-824-5308, e-mail Steve.Branstetter@noaa.gov.

SUPPLEMENTARY INFORMATION: The reef fish fishery of the Gulf of Mexico is managed under the Fishery Management Plan for the Reef Fish Resources of the Gulf of Mexico (FMP). The FMP was prepared by the Gulf of Mexico Fishery Management Council (Council) and is implemented under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 622. These regulations set the recreational quota for Gulf greater amberjack at 1,368,000 lb (620,514 kg), round weight, for the current fishing year, January 1, through December 31, 2009.

Background

Constraining harvest to the quota is crucial to meeting the legal requirements to prevent and end overfishing and rebuild greater amberjack in the Gulf of Mexico. On August 4, 2008, new fishing regulations were implemented by NMFS (73 FR 38139) to reduce the harvest and discard of greater amberjack in the Gulf reef fish fishery. Regulatory changes for recreational greater amberjack included implementing a quota of 1,368,000 lb (620,514 kg), round weight and accountability measures.

Using reported landings for 2009, NMFS projects the 2009 recreational greater amberjack quota will be met on October 24, 2009. Therefore, in accordance with 50 CFR 622.43(a), NMFS is closing the recreational fishery for greater amberjack in the Gulf EEZ, effective 12:01 a.m. local time on October 24, 2009. During the closure, the bag and possession limit for greater amberjack in or from the Gulf EEZ is zero. In addition to the Gulf EEZ closure, as specified in 50 CFR 622.4(a)(1)(iv), a person aboard a vessel for which a Federal charter vessel/headboat permit for Gulf reef fish has

been issued must also abide by these closure provisions in state waters. The closure is intended to prevent overfishing and increase the likelihood that the 2009 quota will not be exceeded. The recreational fishery for greater amberjack will reopen on January 1, 2010, the beginning of the 2010 recreational fishing year.

Classification

This action responds to the best available information recently obtained from the fishery. The AA for Fisheries, NOAA, finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth in 5 U.S.C. 553(b)(3)(B). Such procedures would be unnecessary because the rule implementing the quota and the associated requirement for closure of the fishery when the quota is reached or projected to be reached already has been subject to notice and comment, and all that remains is to notify the public of the closure.

Providing prior notice and opportunity for public comment on this action would be contrary to the public interest. It would be contrary to the public interest because any delay in the closure of this fishery could result in the recreational quota for greater amberjack being exceeded, which, in turn, would trigger the accountability measure for greater amberjack. The accountability measure states that if recreational landings exceed the quota, NMFS will file a notification with the Office of the **Federal Register**, at or near the beginning of the following fishing year, to reduce the length of the recreational fishing season for the following fishing year by the amount necessary to recover the overage from the prior fishing year. Reducing the length of the following fishing season would be disruptive to business plans and would provide less flexibility to fishermen for when they could harvest the quota.

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

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

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

Dated: October 16, 2009.

Emily H. Menashes,

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

[FR Doc. E9-25449 Filed 10-19-09; 4:15 pm]

BILLING CODE 3510-22-S

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration****50 CFR Part 622**

[Docket No. 001005281–0369–02]

RIN 0648–XS51

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Coastal Migratory Pelagic Resources of the Gulf of Mexico and South Atlantic; Closure

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS closes the commercial fishery for king mackerel in the exclusive economic zone (EEZ) in the northern Florida west coast subzone of the Gulf of Mexico. This closure is necessary to protect the Gulf king mackerel resource.

DATES: The closure is effective 12:01 a.m., local time, October 24, 2009, through June 30, 2010.

FOR FURTHER INFORMATION CONTACT: Dr. Steve Branstetter, 727–551–5796, fax: 727–824–5308, e-mail: Steve.Branstetter@noaa.gov.

SUPPLEMENTARY INFORMATION: The fishery for coastal migratory pelagic fish (king mackerel, Spanish mackerel, cero, cobia, little tunny, and, in the Gulf of Mexico only, dolphin and bluefish) is managed under the Fishery Management Plan for the Coastal Migratory Pelagic Resources of the Gulf of Mexico and South Atlantic (FMP). The FMP was prepared by the Gulf of Mexico and South Atlantic Fishery Management Councils (Councils) and is implemented under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 622.

On April 27, 2000, NMFS implemented the final rule (65 FR 16336, March 28, 2000) that divided the Florida west coast subzone of the

eastern zone into northern and southern subzones, and established their separate quotas. The quota for the northern Florida west coast subzone is 168,750 lb (76,544 kg) (50 CFR 622.42(c)(1)(i)(A)(2)(ii)).

Under 50 CFR 622.43(a), NMFS is required to close any segment of the king mackerel commercial fishery when its quota has been reached, or is projected to be reached, by filing a notification with the Office of the **Federal Register**. NMFS has determined the commercial quota of 168,750 lb (76,544 kg) for Gulf group king mackerel in the northern Florida west coast subzone will be reached by October 24, 2009. Accordingly, the commercial fishery for Gulf group king mackerel in the northern Florida west coast subzone is closed effective 12:01 a.m., local time, October 24, 2009, through June 30, 2010, the end of the fishing year.

The Florida west coast subzone is that part of the eastern zone south and west of 25°20.4' N. lat. (a line directly east from the Miami-Dade County, FL boundary). The Florida west coast subzone is further divided into northern and southern subzones. The northern subzone is between 26°19.8' N. lat. (a line directly west from the Lee/Collier County, FL boundary) and 87°31.06' W. long. (a line directly south from the Alabama/Florida boundary).

Except for a person aboard a charter vessel or headboat, during the closure, no person aboard a vessel for which a commercial permit for king mackerel has been issued may fish for or retain Gulf group king mackerel in the EEZ in the closed subzone. A person aboard a vessel that has a valid charter vessel/headboat permit for coastal migratory pelagic fish may continue to retain king mackerel in or from the closed zones or subzones under the bag and possession limits set forth in 50 CFR 622.39(c)(1)(ii) and (c)(2), provided the vessel is operating as a charter vessel or headboat. A charter vessel or headboat that also has a commercial king mackerel permit is considered to be operating as a charter vessel or headboat when it carries a passenger who pays a fee or when there are more than three

persons aboard, including operator and crew.

During the closure, king mackerel from the closed subzone taken in the EEZ, including those harvested under the bag and possession limits, may not be purchased or sold. This prohibition does not apply to trade in king mackerel from the closed subzone that were harvested, landed ashore, and sold prior to the closure and were held in cold storage by a dealer or processor.

Classification

This action responds to the best available information recently obtained from the fisheries. The Assistant Administrator for Fisheries, NOAA, finds that the need to immediately implement this action to close the fishery constitutes good cause to waive the requirements to provide prior notice and opportunity for public comment pursuant to the authority set forth in 5 U.S.C. 553(b)(3)(B), as such procedures would be unnecessary and contrary to the public interest. Such procedures would be unnecessary because the rule itself already has been subject to notice and comment, and all that remains is to notify the public of the closure.

NMFS also finds good cause that the implementation of this action cannot be delayed for 30 days. There is a need to implement this measure in a timely fashion to prevent an overrun of the commercial quota of Gulf king mackerel in the northern Florida west coast subzone, given the capacity of the fishing fleet to harvest the quota quickly. Any delay in implementing this action would be contrary to the Magnuson-Stevens Act and the FMP. Accordingly, under 5 U.S.C. 553(d)(3), a delay in the effective date is waived.

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

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

Dated: October 16, 2009.

Emily H. Menashes,

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

[FR Doc. E9–25450 Filed 10–19–09; 4:15 pm]

BILLING CODE 3510–22–S

Proposed Rules

Federal Register

Vol. 74, No. 203

Thursday, October 22, 2009

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.

FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

5 CFR Parts 1604, 1651, 1653, and 1690

Uniformed Services Accounts; Death Benefits; Court Orders and Legal Processes Affecting Thrift Savings Plan Accounts; Thrift Savings Plan

AGENCY: Federal Retirement Thrift Investment Board.

ACTION: Proposed rules with request for comments.

SUMMARY: The Federal Retirement Thrift Investment Board (Agency) proposes to amend its regulations regarding uniformed services accounts to conform with mandatory tax provisions as well as current record keeping practices and allow only for *pro rata* court-ordered payments.

The Agency proposes to amend its regulations regarding death benefits to provide for a clear process by which children of participants can establish parentage.

The Agency proposes to amend its court order regulations so that when a court order directs that payment is to include earnings, the Agency is able to make a payment which calculates the payee's award amount based on the current price of the shares he/she was awarded.

The Agency also proposes to amend its court order regulations to remove a provision which permits courts to direct payment from only the tax-exempt balance of a uniformed services account.

The Agency proposes to amend its regulations at part 1690, subpart B, to add a regulation outlining the circumstances under which a TSP account may be frozen.

DATES: Comments must be received on or before November 23, 2009.

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

- Federal Rulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Mail: Office of General Counsel, Attn: Thomas Emswiler, Federal

Retirement Thrift Investment Board, 1250 H Street, NW., Washington, DC 20005.

- Hand Delivery/Courier: The address for sending comments by hand delivery or courier is the same as that for submitting comments by mail.
- Facsimile: Comments may be submitted by facsimile at (202) 942-1676.

The most helpful comments explain the reason for any recommended change and include data, information, and the authority that supports the recommended change. We will post all substantive comments (including any personal information provided) without change (with the exception of redaction of SSNs, profanities, et cetera) on <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Tim Carey at 202-942-1666 or Laurissa Stokes at 202-942-1645.

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

Uniformed Services Accounts

The Agency proposes to amend its regulations regarding uniformed services accounts, and, specifically, its provisions relating to the division of a uniformed services account pursuant to a court order or legal process. The Agency seeks to remove a provision suggesting that courts could direct the Plan to make a court-ordered payment other than one that is *pro rata* from both taxable and tax-exempt contributions.

Uniformed services accounts are unique in that some or all of a uniformed services member's contributions may derive from tax-exempt income as a result of the combat zone tax exclusion. In 2001, the Agency issued final regulations regarding the uniformed services' participation in the TSP. Among many changes, the Agency determined that "the TSP can honor a

court order or legal process that apportions combat zone (tax-exempt) contributions between the participant and the payee," and, therefore, the final version of 5 CFR 1604.9(b) regarding court-ordered payments from a uniformed services member's account stated that payment will be made *pro rata* from all sources "unless the court order or legal process directs otherwise." (66 FR 50716, October 4, 2001).

The Agency recently analyzed its authority and record keeping capability to issue payments from, as the regulation suggests, only one source of contributions in a uniformed services participant's account. The Agency has concluded that the Internal Revenue Code (I.R.C.) permits only *pro rata* payments from both taxable and tax-exempt funds, and that a court cannot direct the Plan to make a payment from, for example, only tax-exempt funds.

Specifically, I.R.C. sections 72 and 402(e)(1)(A) preclude an allocation of basis pursuant to a court order if such allocation is other than *pro rata*. In particular, for purposes of determining tax liability, a spousal alternate payee is treated the same as the participant and, therefore, a distribution to a spouse or former spouse made pursuant to a court order must be made *pro rata* from taxable and tax-exempt amounts in a uniformed services account. 26 U.S.C. 402(e)(1)(A). Therefore, the Agency's regulation permitting courts to order a payment other than *pro rata* is not permitted by the I.R.C. and must be changed.

Additionally, the Agency's record keeping system cannot issue a payment from only one source of funds because it is programmed to make all payments from uniformed services accounts on a *pro rata* basis from taxable and tax-exempt balances. Therefore, changing this regulation to remove the language which suggests a court could direct the Agency to issue a payment other than one which is *pro rata* is not only technically correct but also reflects current record keeping processes.

Death Benefits

The Agency proposes to amend its regulations regarding death benefits, and, in particular, its regulation regarding payment to a participant's child or children. Specifically, the Agency seeks to clarify the documentation children should submit

in the event that the identity of their father or mother is in dispute or unclear.

As familial matters, including guidelines related to parentage, are rooted in state, not Federal, law, the Agency cannot adjudicate or otherwise determine matters of paternity or maternity. In support of their contention that they are the proper beneficiary of their parent's account, children of deceased participants often submit insufficient or otherwise unclear documentation (e.g., copies of obituaries and personal mementos). A lack of guidance regarding which documents to submit in support of parentage adds unnecessary time and inconvenience to the processing of death benefit determinations.

The Agency, therefore, proposes to augment its death benefits regulations to describe the documentation it requires in support of a purported child's claim that a participant was his or her parent. Specifically, the Agency requests that affected children submit a court order or administrative finding or documentation which would establish parentage in the state in which the participant resided prior to his death.

Court Orders and Legal Processes Affecting Thrift Savings Plan Accounts

The Agency is proposing to change its court order regulations to allow for court-awarded payments which account for investment earnings and losses as well as to reflect the previously-discussed requirement that all payments from participants' accounts be paid *pro rata*.

Currently, in order for the Agency to take into account investment losses, a court order has to divide the account as of the date of distribution or identify a fixed amount that the parties agreed upon. Further, per the Agency's regulations, if a court order specifies that earnings are to be awarded and no specific rate is provided, even when an account experiences investment losses, the Agency awards earnings using its Government Securities Investment (G) Fund rate. 5 CFR 1653.4(f)(3).

The Agency, which receives many court orders directing that payments reflect earnings and losses until the date of distribution, proposes to change its regulations so that the division of an account factors in the current price of those shares included in a payee's award amount.

In particular, if earnings, defined to include losses, are requested and a rate is not specified, the Agency proposes to determine the amount to be awarded by determining the payee's award amount (e.g., the percentage or fraction of the participant's account), and, based on the

participant's investment allocation as of the effective date of the court order, the number and composition of shares that the payee's award amount would have purchased as of the effective date. (Determining the shares as of the effective date of the court order, and not a later date, preserves the court's intent and protects the payee from investment decisions made by the participant after the effective date of the court order.) The Agency will then multiply the price per share as of the payment date, which is generally two business days prior to the date of the award's disbursement, by the number and composition of shares comprising the payee's award amount as of the court order's effective date.

The Agency believes that this calculation will result in more equitable awards as well as more efficient court order processing as parties are not required to return to court for additional or clarifying language.

As previously discussed, the Agency also proposes to amend its court order and legal process regulations in order to conform with the I.R.C. and current record keeping procedures. In particular, the Agency seeks to remove language from § 1653.5(d) which states that a court may specify a particular payment from the tax-exempt balance of a uniformed services account. Please see the Supplemental Information discussion regarding Uniformed Services Accounts for an overview as to why the Agency is proposing to remove such language.

Thrift Savings Plan

The Agency wishes to add a regulation outlining the circumstances under which a participant's account may be frozen and when access to the Agency's web site and ThriftLine may be blocked. Though uncommon, freezes (or administrative holds) prevent a participant from withdrawing funds, including loans, from his or her account, and, therefore, the Agency seeks to place its participants on notice regarding the circumstances under which such a hold may occur and also the consequences of such a hold.

Regulatory Flexibility Act

I certify that this regulation will not have a significant economic impact on a substantial number of small entities.

Paperwork Reduction Act

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

Unfunded Mandates Reform Act of 1995

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

Submission to Congress and the Government Accountability Office

Pursuant to 5 U.S.C. 810(a)(1)(A), the Agency submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States before publication of this rule in the **Federal Register**. This rule is not a major rule as defined at 5 U.S.C. 804(2).

List of Subjects

5 CFR Part 1604

Military personnel, Pensions, Retirement.

5 CFR Part 1651

Claims, Government employees, Pensions, Retirement.

5 CFR Part 1653

Alimony, Child support, Claims, Government employees, Pensions, Retirement.

5 CFR Part 1690

Government employees, Pensions, Retirement.

Gregory T. Long,

Executive Director, Federal Retirement Thrift Investment Board.

For the reasons stated in the preamble, the Agency proposes to amend 5 CFR chapter VI as follows:

PART 1604—UNIFORMED SERVICES ACCOUNTS

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

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

2. Amend § 1604.9 to revise paragraph (b) to read as follows:

§ 1604.9 Court orders and legal processes.

* * * * *

(b) *Combat zone contributions.* If a service member account contains combat zone contributions, the payment will be made pro rata from all sources.

* * * * *

PART 1651—DEATH BENEFITS

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

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

4. Amend § 1651.1 to add the definition of “Administrative finding”, in alphabetical order, in paragraph (b) to read as follows:

§ 1651.1 Definitions.

* * * * *

(b) * * *

Administrative finding means an evidence-based determination reached by a hearing, inquiry, investigation, or trial before an administrative agency of competent jurisdiction in any State, territory or possession of the United States.

* * * * *

5. Amend § 1651.6 to add a paragraph (d) to read as follows:

§ 1651.6 Child or children.

* * * * *

(d) *Parentage disputes.* If the identity of the father or mother of a child is in dispute or otherwise unclear (e.g., only one parent is listed on a birth certificate), the purported child must submit to the TSP either:

(1) A court order or other administrative finding establishing parentage; or

(2) Documentation sufficient for establishing parentage under the law of the state in which the participant was domiciled at the time of death.

PART 1653—COURT ORDERS AND LEGAL PROCESSES AFFECTING THRIFT SAVINGS PLAN ACCOUNTS

6. The authority citation for part 1653 continues to read as follows:

Authority: 5 U.S.C. 8435, 8436(b), 8437(e), 8439(a)(3), 8467, 8474(b)(5) and 8474(c)(1).

7. Amend § 1653.1 to add the definitions of “Payment date” and “TSP investment earnings or earnings”, in alphabetical order in paragraph (b) to read as follows:

§ 1653.1 Definitions.

* * * * *

(b) * * *

* * * * *

Payment date refers to the date on which earnings are determined and is generally two business days prior to the date of an award’s disbursement.

* * * * *

TSP investment earnings or earnings means both positive and negative fund performance attributable to differences in TSP fund share prices.

* * * * *

8. Amend § 1653.4 to revise paragraph (f)(3) and remove paragraph (f)(4) to read as follows:

§ 1653.4 Calculating entitlements.

* * * * *

(f) * * *

(3) If earnings are awarded and the rate is not specified, the Agency will calculate the amount to be awarded by:

(i) Determining the payee’s award amount (e.g., the percentage or fraction of the participant’s account);

(ii) Determining, based on the participant’s investment allocation as of the effective date of the court order, the number and composition of shares that the amount in paragraph (f)(3)(i) of this section would have purchased as of the effective date; and

(iii) Multiplying the price per share as of the payment date by the number and composition of shares calculated in paragraph (f)(3)(ii) of this section.

* * * * *

§ 1653.5 [Amended]

9. Amend § 1653.5 by removing the last sentence of paragraph (d).

PART 1690—THRIFT SAVINGS PLAN

10. The authority citation for part 1690 continues to read as follows:

Authority: 5 U.S.C. 8474.

10. Add § 1690.15 to read as follows:

§ 1690.15 Freezing an account—administrative holds.

(a) The TSP may freeze (e.g., place an administrative hold on) a participant’s account for any of the following reasons:

(1) Pursuant to a qualifying retirement benefits court order as set forth in part 1653 of this chapter;

(2) Pursuant to a request from the Department of Justice under the Mandatory Victims Restitution Act;

(3) Upon the death of a participant;

(4) Upon suspicion or knowledge of fraudulent account activity or identity theft;

(5) In response to litigation pertaining to an account;

(6) For operational reasons (e.g., to correct a processing error or to stop payment on a check when account funds are insufficient);

(7) Pursuant to a written request from a participant; and

(8) For any other reason the TSP deems prudent.

(b) An account freeze (i.e., administrative hold) prohibits a participant from withdrawing funds, including loans, from his or her account. The participant continues to have the capability to conduct all other transactions including making

contributions, changing contribution allocations, and making interfund transfers.

(c) The Agency will notify the participant that his or her account has been frozen unless it determines it prudent to not notify the participant that his or her account has been frozen.

(d) A participant may block on-line and ThriftLine access to his or her account by writing to the TSP or by submitting a request at <http://www.tsp.gov>.

(e) A participant may remove a participant-initiated freeze (administrative hold) by submitting a notarized request to the TSP.

[FR Doc. E9–25426 Filed 10–21–09; 8:45 am]

BILLING CODE 6760–01–P

DEPARTMENT OF AGRICULTURE**Food Safety and Inspection Service****9 CFR Parts 321, 332, and 381**

[Docket No. FSIS–2008–0039]

RIN 0583–AD37

Cooperative Inspection Programs: Interstate Shipment of Meat and Poultry Products

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice of public meetings.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing that it will hold two public meetings on proposed regulations that it recently published to implement a new voluntary cooperative program under which State-inspected establishments with 25 or fewer employees will be eligible to ship meat and poultry products in interstate commerce (74 FR 47648, September 16, 2009). To provide stakeholders with ready access to the public meetings, FSIS will conduct these meetings by teleconference. This notice provides information on the public meetings.

DATES: The teleconferences will be held on October 27, 2009, from 12:30 p.m. to 4:30 p.m. EST, and on November 5, 2009, from 12:30 p.m. to 4:30 p.m. EST.

ADDRESSES:

Registration: Pre-registration for these meetings is required. To pre-register, access the FSIS Web site, at http://www.fsis.usda.gov/News/Meetings_&_Events/. Call-in information will be provided via e-mail to pre-registered participants. We are also asking that anyone interested in making a public comment during the

teleconference indicate so on the registration form.

Public Comment: In addition to these teleconferences, interested persons may submit comments on the proposed rule on or before November 16, 2009, using either of the following methods:

Federal eRulemaking Portal: Go to <http://www.regulations.gov> and follow the online instructions at that site for submitting comments.

Mail, including floppy disks or CD-ROMs, and hand- or courier-delivered items: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, Room 2-2127 George Washington Carver Center, 5601 Sunnyside Avenue, Beltsville, MD 20705, MAILSTOP 5272.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2008-0039. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to: <http://www.regulations.gov>.

Docket: For access to background documents or comments received, go to the FSIS Docket Room at the address listed above between 8:30 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: For technical information: contact Philip Derfler, Assistant Administrator, Office of Policy and Program Development, at (202) 720-2709, or by fax at (202) 720-2025.

For teleconference information: contact Sharon Randle, Public Affairs Specialist, Congressional and Public Affairs Office, by telephone at (202) 720-6755, or by e-mail to sharon.randle@fsis.usda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On September 16, 2009, FSIS published a proposed rule to implement a new voluntary cooperative program under which State-inspected establishments with 25 or fewer employees will be eligible to ship meat and poultry products in interstate commerce. In participating States, State-inspected establishments that are selected, to take part in this program will be required to comply with all Federal standards under the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA), as well as with all State standards. Establishments selected for the proposed interstate shipment program will receive inspection services from State inspection personnel that have been trained in the enforcement of the

FMIA and PPIA. Meat and poultry products produced under the program that have been inspected and passed by designated State personnel will bear an official Federal mark of inspection and will be permitted to be distributed in interstate commerce. FSIS will provide oversight and enforcement of the program. Section 11015 of the Food, Conservation, and Energy Act, enacted on June 18, 2008, (the 2008 Farm Bill), amended the FMIA and PPIA to provide for these cooperative programs.

State participation in the proposed cooperative interstate shipment program will be limited to States that have cooperative State meat or poultry inspection programs under which products are produced for distributed solely within the State. Under the existing cooperative inspection programs, States enforce inspection and sanitation requirements that must be "at least equal to" those in the FMIA and the PPIA. Twenty-seven states have cooperative agreements to administer these meat or poultry products inspection programs. These States inspect about 1,900 small and very small establishments.

Under the proposed regulations, establishments will apply for the new program through the States. FSIS will coordinate with States to select establishments to participate in the program. The proposed interstate shipment program is intended to supplement, not replace, the existing cooperative State inspection programs.

II. Purpose of the Meeting and Agenda

To provide the public with an opportunity to comment on the proposed rule, FSIS will hold two public meetings by teleconference. The first meeting will be held on October 27, 2009, and the second will be held on November 5, 2009. The teleconference format is being used to provide individuals with easier access to the meeting, particularly those who may lack the resources or time to attend a meeting in person. The teleconference format is also economically beneficial to all stakeholders. Interested persons are encouraged to join the teleconference at or near the start time. FSIS may end the teleconference early if participants are no longer calling in to make comments. The agenda and other documents related to the meetings will be made available for viewing prior to the meeting at FSIS: http://www.fsis.usda.gov/News/Meetings_&_Events/.

III. Transcripts

As soon as the meeting transcripts are available, they will be accessible at

<http://www.regulations.gov>. The transcripts may be viewed at FSIS Docket Room, U.S. Department of Agriculture, Food Safety and Inspection Service, Room 2-2127 George Washington Carver Center, 5601 Sunnyside Avenue, Beltsville, MD 20705.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to ensure that the public and in particular minorities, women, and persons with disabilities, are aware of this notice, FSIS will announce it on-line through the FSIS Web page located at: http://www.fsis.usda.gov/regulations/2009_Notices_Index/. FSIS also will make copies of this **Federal Register** publication available through the *FSIS Constituent Update*, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The *Update* is communicated via Listserv, a free e-mail subscription service delivered to industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals who have requested to be included. The *Update* also is available on the FSIS Web page. Through Listserv and the Web page, FSIS is able to provide information to a much broader, more diverse audience.

In addition, FSIS offers an e-mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at http://www.fsis.usda.gov/news_and_events/email_subscription/. Options range from recalls, export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

Done at Washington, DC, on October 20, 2009.

Alfred V. Almanza,
Administrator, FSIS.

[FR Doc. E9-25522 Filed 10-20-09; 4:15 pm]

BILLING CODE 3410-DM-P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 39**

[Docket No. FAA-2009-0953; Directorate Identifier 2009-SW-45-AD]

RIN 2120-AA64

Airworthiness Directives; MD Helicopters, Inc. Model MD-900 Helicopters

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes superseding an existing airworthiness directive (AD) for MD Helicopters, Inc. (MDHI) Model MD-900 helicopters. That AD currently requires applying serial numbers to certain parts, increasing the life limit for various parts, maintaining a previously established life limit for a certain vertical stabilizer control system (VSCS) bellcrank assembly and bellcrank arm, and correcting the part number for the VSCS bellcrank arm. This proposal would require the same actions, except it would reduce the life limit of the swashplate spherical slider bearing (slider bearing). It would further correct what was described as a "bellcrank arm" life limit in the current AD and correctly describe it as another "bellcrank assembly" life limit. This proposal is prompted by two reports of cracks in the slider bearing that occurred well before the previously increased retirement life of 2,030 hours time-in-service (TIS) was reached. The actions specified by the proposed AD are intended to establish appropriate life limits for various parts, and to prevent fatigue failure of those parts and subsequent loss of control of the helicopter.

DATES: Comments must be received on or before December 21, 2009.

ADDRESSES: Use one of the following addresses to submit comments on this proposed AD:

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

Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

You may get the service information identified in this AD from MD Helicopters Inc., Attn: Customer Support Division, 4555 E. McDowell Rd., Mail Stop M615, Mesa, Arizona 85215-9734, telephone 1-800-388-3378, fax 480-346-6813, or on the web at www.mdhelicopters.com.

You may examine the comments to this proposed AD in the AD docket on the Internet at <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Roger Durbin, Aviation Safety Engineer, FAA, Los Angeles Aircraft Certification Office, Airframe Branch, 3960 Paramount Blvd., Lakewood, California 90712, telephone (562) 627-5233, fax (562) 627-5210.

SUPPLEMENTARY INFORMATION:**Comments Invited**

We invite you to submit any written data, views, or arguments regarding this proposed AD. Send your comments to the address listed under the caption **ADDRESSES**. Include the docket number "FAA-2009-0953, Directorate Identifier 2009-SW-45-AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the proposed AD. We will consider all comments received by the closing date and may amend the proposed AD in light 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 with FAA personnel concerning this proposed rulemaking. Using the search function of our docket web site, you can find and read the comments to any of our dockets, including the name of the individual who sent or signed the comment. You may review the DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477-78).

Examining the Docket

You may examine the docket that contains the proposed AD, any comments, and other information in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Operations office (telephone (800) 647-5527) is located in Room W12-140 on the ground floor of the West Building at the street address

stated in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

Discussion

On June 17, 1997, we issued AD 97-13-09, Amendment 39-10056 (62 FR 34163, June 25, 1997), to require applying a specified serial number (S/N) to the following parts: for helicopters with S/N 0002 through 0012, to the mid-forward truss assembly, P/N 900F2401200-102, and to the forward and aft deck fitting assemblies, P/N 900F2401500-103 and 900F2401600-103, respectively; for helicopters with S/N 0002 through 0048, to the VSCS bellcrank assemblies, P/N 900F2341712-101 and P/N 900FP341712-103, and to the mid-aft truss strut assembly, P/N 900F2401300-103. That AD also reduced the life limits for the nonrotating swashplate assembly, P/N 900C2010192-105, -107, -109, and -111, from 8,300 hours TIS to 554 hours TIS; the collective drive link assembly, P/N 900C2010207-101, from 3,900 hours TIS to 1,480 hours TIS; and the slider bearing, P/N 900C3010042-103, from 2,100 hours TIS to 480 hours TIS. Finally, that AD established life limits for the bellcrank assembly, P/N 900FP341712-103, and the bellcrank arm, P/N 900F2341713-101 (used in the bellcrank assembly, P/N 900F2341712-101), of 2,700 hours TIS. That AD was prompted by an analysis that indicated a need to reduce the life limits on several parts and by the addition of non-serialized parts to the life-limited parts list. The requirements of that AD were intended to establish new life limits for various parts and reduce the existing life limits on other parts.

On July 28, 1999, we issued superseding AD 99-16-13, Amendment 39-11248 (64 FR 42824, August 6, 1999), to correct the P/N for the bellcrank arm from P/N 900F2341713-101 to P/N 900F2341712-101, and to increase the life limits for the nonrotating swashplate, P/N 900C2010192-105, -107, -109, or -111, from 554 hours TIS to 1,800 hours TIS; the collective drive link assembly, P/N 900C2010207-101, from 1,480 hours TIS to 3,307 hours TIS; and the slider bearing, P/N 900C3010042-103, from 480 hours TIS to 2,030 hours TIS, and maintaining the 2,700 hours TIS for the bellcrank assembly and bellcrank arm. AD 99-16-13 was prompted by both the need to correct a P/N as well as additional analyses (modified fatigue spectrums, fatigue tests, and flight strain data) supporting an increase in the life limits for certain parts. The requirements of that AD are intended to

increase the life limits of various parts, correct the bellcrank arm P/N, and specify applying serial numbers to various parts.

Since issuing AD 99-16-13, we have received two reports from the manufacturer of cracks in the attachment ear of the slider bearing, P/N 900C3010042-103. A review of the service history and a further review of the design data for the slider bearing now indicate that a reduced life limit is required to maintain continued operational safety. The manufacturer has made available an alternate replacement slider bearing, P/N 900C3010042-105, that has improved durability characteristics and an increased life limit of 12,807 hours TIS. Further, we have determined that even though we corrected P/N "900F2341713-101" to read "900F2341712-101" in AD 99-16-13, we incorrectly described the part as a "bellcrank arm" in both AD 99-16-13 and AD 97-13-09. The correct nomenclature for P/N 900F2341712-101 is "bellcrank assembly." We propose to correct that error in this action.

We have reviewed MD Helicopters Service Bulletin SB900-096, dated February 28, 2005, which contains a reduction of the life limit of the slider bearing from 2,030 hours TIS to 700 hours TIS.

This previously described unsafe condition is likely to exist or develop on other helicopters of the same type design. Therefore, the proposed AD would supersede AD 99-16-13 to decrease the life limit of the slider bearing from 2,030 hours TIS to 700 hours TIS. Additionally, this AD changes the nomenclature for P/N 900F2341712-101 from bellcrank arm to bellcrank assembly. The proposed AD would also retain the requirements of the existing AD to apply serial numbers to various parts, and retain the life limits of various other parts.

We estimate that this proposed AD would affect 27 helicopters of U.S. registry and that it would take approximately 2.5 work hours per helicopter to accomplish the serialization of the affected parts at an average rate of \$80 per work hour. Additionally, it is estimated that 8 of those aircraft will require replacement of the slider bearing, which will require approximately 7 work hours to accomplish at an average rate of \$80 per work hour. Required parts would cost \$11,080 per helicopter for the slider bearing. Based on these figures, we estimate the total cost impact of the proposed AD on U.S. operators to be \$98,520.

Regulatory Findings

We have determined that this proposed AD would not have federalism implications under Executive Order 13132. Additionally, 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 that the proposed regulation:

1. Is not a "significant regulatory action" under Executive Order 12866;
2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and
3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a draft economic evaluation of the estimated costs to comply with this proposed AD. See the AD docket to examine the draft economic evaluation.

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.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (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. Section 39.13 is amended by removing Amendment 39-11248 (64 FR 42824, August 6, 1999), and by adding a new airworthiness directive (AD), to read as follows:

MD Helicopters, Inc. Model MD-900

Helicopters: Docket No. FAA-2009-0953; Directorate Identifier 2009-SW-45-AD. Supersedes AD 99-16-13, Amendment 39-11248, Docket No. 98-SW-42-AD.

Applicability

MD-900 helicopters, certificated in any category.

Compliance

Required as indicated, unless accomplished previously.

To establish appropriate life limits for various parts, and to prevent fatigue failure of those parts and subsequent loss of control of the helicopter, accomplish the following:

- (a) Remove from service as follows:
 - (1) The nonrotating swashplate assembly, part number (P/N) 900C2010192-105, -107, -109, or -111, on or before 1,800 hours time-in-service (TIS).
 - (2) The collective drive link assembly, P/N 900C2010207-101, on or before 3,307 hours TIS.
 - (3) The swashplate spherical slider bearing, P/N 900C3010042-103, on or before 700 hours TIS.
 - (4) The vertical stabilizer control system (VSCS) bellcrank assembly, P/N 900FP341712-103, and bellcrank assembly, P/N 900F2341712-101, on or before 2,700 hours TIS.

(b) Within 100 hours TIS:

- (1) For Model MD-900 helicopters with serial numbers (S/N) 900-00002 through 900-00012, apply the appropriate S/N to the mid-forward truss assembly, P/N 900F2401200-102, and the forward and aft deck-fitting assemblies, P/N 900F2401500-103 and P/N 900F2401600-103.

- (2) For Model MD-900 helicopters with S/N 900-00002 through 900-00048, apply S/N to the left and right VSCS bellcrank assemblies, P/N 900F2341712-101 and P/N 900FP341712-103, and the mid-aft truss strut assembly, P/N 900F2401300-103.

- (3) Apply the S/N, as specified in paragraphs (b)(1) and (b)(2) of this AD, adjacent to the existing P/N, as listed in Appendix A of this AD, using permanent ink or paint. When dry, apply a clear coat over the S/N.

(c) This AD revises the Airworthiness Limitations Section of the MD-900 Maintenance Manual by increasing the life limits for certain parts and reducing the life limit of the slider bearing.

Note: The Airworthiness Limitations Section of the MD-900 Rotorcraft Maintenance Manual, Reissue 1, Revision 25,

dated April 16, 2006, and MD Helicopters Service Bulletin SB900-096, dated February 28, 2005, pertain to the subject of this AD. To request a different method of compliance

or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Contact the Manager, Los Angeles Aircraft Certification Office, FAA, for information

about previously approved alternative methods of compliance.

BILLING CODE 4910-13-P

Appendix A
VSCS Bellcrank, Mid-Aft Strut and Deck Fitting Serialization

Serial Number To Be Applied			
Aircraft Ser. No.	VSCS Bellcrank Assembly 900F2341712-101 and 900FP341712-103		Strut Assy, Mid-Aft 900F2401300-103
	LH VSCS	RH VSCS	
0002	009999-0001	009999-0002	Previously serialized
0008	009999-0003	009999-0004	Previously serialized
0010	009999-0005	009999-0006	Previously serialized
0011	009999-0007	009999-0008	Previously serialized
0012	009999-0009	009999-0010	Previously serialized
0013	009999-0011	009999-0012	009999-0006
0014	009999-0013	009999-0014	009999-0007
0015	009999-0015	009999-0016	009999-0008
0016	009999-0017	009999-0018	009999-0009
0017	009999-0019	009999-0020	009999-0010
0018	009999-0021	009999-0022	009999-0011
0019	009999-0023	009999-0024	009999-0012
0020	009999-0025	009999-0026	009999-0013
0021	009999-0027	009999-0028	009999-0014
0022	009999-0029	009999-0030	009999-0015
0023	009999-0031	009999-0032	009999-0016
0024	009999-0033	009999-0034	009999-0017
0025	009999-0035	009999-0036	009999-0018
0026	009999-0037	009999-0038	009999-0019
0027	009999-0039	009999-0040	009999-0020
0028	009999-0041	009999-0042	009999-0021
0029	009999-0043	009999-0044	009999-0022
0030	009999-0045	009999-0046	009999-0023

Appendix A (continued)

Serial Number To Be Applied (Cont.)			
Aircraft Ser. No.	VSCS Bellcrank Assembly 900F2341712-101 and 900FP341712-103		Strut Assy, Mid-Aft 900F2401300-103
	LH VSCS	RH VSCS	
0031	009999-0047	009999-0048	009999-0024
0032	009999-0049	009999-0050	009999-0025
0033	009999-0051	009999-0052	009999-0026
0034	009999-0053	009999-0054	009999-0027
0035	009999-0055	009999-0056	009999-0028
0036	009999-0057	009999-0058	009999-0029
0037	009999-0059	009999-0060	009999-0030
0038	009999-0061	009999-0062	009999-0031
0039	009999-0063	009999-0064	009999-0032
0040	009999-0065	009999-0066	009999-0033
0041	009999-0067	009999-0068	009999-0034
0042	009999-0069	009999-0070	009999-0035
0043	009999-0071	009999-0072	009999-0036
0044	009999-0073	009999-0074	009999-0037
0045	009999-0075	009999-0076	009999-0038
0046	009999-0077	009999-0078	009999-0039
0047	009999-0079	009999-0080	009999-0040
0048	009999-0081	009999-0082	009999-0041

NOTE - Aircraft 00002 thru 00012 are equipped with 900F2401300-101 Mid-Aft Strut Assemblies. These strut assemblies were previously serialized, therefore, no action is required. Refer to CSP-900RMM-2, Section 04-00-00, for retirement time of this part.

Serial Number To Be Applied			
Aircraft Serial No.	Strut Assembly, Mid-Fwd Truss (900F2401200-102)	Deck Fitting Assembly, Fwd (900F2401500-103)	Deck Fitting Assembly, Aft (900F2401600-103)
0002	009999-0001	009999-0001	009999-0001
0008	009999-0002	009999-0002	009999-0002
0010	009999-0003	009999-0003	009999-0003
0011	009999-0004	009999-0004	009999-0004
0012	009999-0005	009999-0005	009999-0005

Issued in Fort Worth, Texas, on October 8, 2009.

Larry M. Kelly,

Acting Manager, Rotorcraft Directorate,
Aircraft Certification Service.

[FR Doc. E9-25439 Filed 10-21-09; 8:45 am]

BILLING CODE 4910-13-C

**DEPARTMENT OF TRANSPORTATION
Federal Aviation Administration**

14 CFR Part 39

[Docket No. FAA-2009-0987; Directorate Identifier 2009-CE-054-AD]

RIN 2120-AA64

Airworthiness Directives; AeroSpace Technologies of Australia Pty Ltd Models N22B, N22S, and N24A Airplanes

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

ACTION: Notice of proposed rulemaking (NPRM).

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

Late in 2002 the manufacturer advised CASA of another Nomad accident which was possibly caused by aileron flutter with the

flaps at 38 degrees. This, along with the other flutter incidents, has resulted in the manufacturer issuing ANMD-57-18 Issue 1 as a precautionary measure while they further investigate the issue.

The manufacturer has now completed their investigation and issued Alert Service Bulletin ANMD-27-53 to modify flap actuation linkages to restore the necessary rigidity to the outboard flap, and hence the aileron. The unacceptable flexibility of the outboard flap mechanism allows flutter to occur in extreme circumstances.

The proposed AD would require actions that are intended to address the unsafe condition described in the MCAI.

DATES: We must receive comments on this proposed AD by December 7, 2009.

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

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

Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov>; or in person at the Docket 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 (telephone (800) 647-5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT:

Doug Rudolph, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329-4059; fax: (816) 329-4090; e-mail: doug.rudolph@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-2009-0987; Directorate Identifier 2009-CE-054-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

On October 13, 2006, we issued AD 2006-21-12, Amendment 39-14797 (71 FR 61636; October 19, 2006). That AD required actions intended to address an unsafe condition on the products listed above.

Since we issued AD 2006-21-12, the manufacturer completed their flutter investigation and issued Nomad Alert Service Bulletin ANMD-27-53, dated February 20, 2008, to modify flap actuation linkages. This modification restores the necessary rigidity to the outboard flap, and hence the aileron.

The Civil Aviation Safety Authority, which is the aviation authority for Australia, has issued AD number AD/GAF-N22/69 Amdt 6, dated September 10, 2009 (referred to after this as "the MCAI"), to correct an unsafe condition for the specified products. The MCAI states:

Late in 2002 the manufacturer advised CASA of another Nomad accident which was possibly caused by aileron flutter with the flaps at 38 degrees. This, along with the other flutter incidents, has resulted in the manufacturer issuing ANMD-57-18 Issue 1 as a precautionary measure while they further investigate the issue.

The manufacturer has now completed their investigation and issued Alert Service Bulletin ANMD-27-53 to modify flap actuation linkages to restore the necessary rigidity to the outboard flap, and hence the aileron. The unacceptable flexibility of the outboard flap mechanism allows flutter to occur in extreme circumstances.

This amendment mandates Alert Service Bulletin ANMD-27-53, which requires modifications to the aircraft, but terminates the limitations imposed by earlier amendments.

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

Relevant Service Information

AeroSpace Technologies of Australia Pty Ltd has issued Nomad Alert Service Bulletin ANMD-27-53, dated February 20, 2008. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

FAA's Determination and Requirements of the Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with this State of Design Authority, 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 and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design.

Differences Between This Proposed AD and the MCAI or Service Information

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

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

Costs of Compliance

We estimate that this proposed AD will affect 15 products of U.S. registry. We also estimate that it would take about 73 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is \$80 per work-hour. Required parts would cost about \$15,100 per product.

Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be \$314,100, or \$20,940 per product.

Authority for This Rulemaking

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

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, Section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures

the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

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

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

1. Is not a "significant regulatory action" under Executive Order 12866;
2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and
3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. The FAA amends § 39.13 by removing Amendment 39-14797 (71 FR 61636; October 19, 2006), and adding the following new AD:

AeroSpace Technologies of Australia Pty Ltd: Docket No. FAA-2009-0987; Directorate Identifier 2009-CE-054-AD.

Comments Due Date

(a) We must receive comments by December 7, 2009.

Affected ADs

(b) This AD supersedes AD 2006-21-12 Amendment 39-14797.

Applicability

(c) This AD applies to Models N22B, N22S, and N24A airplanes, all serial numbers, including airplanes with float/amphibian configuration, certificated in any category.

Subject

(d) Air Transport Association of America (ATA) Code 27: Flight Controls.

Reason

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

Late in 2002 the manufacturer advised CASA of another Nomad accident which was possibly caused by aileron flutter with the flaps at 38 degrees. This, along with the other flutter incidents, has resulted in the manufacturer issuing ANMD-57-18 Issue 1 as a precautionary measure while they further investigate the issue.

The manufacturer has now completed their investigation and issued Alert Service Bulletin ANMD-27-53 to modify flap actuation linkages to restore the necessary rigidity to the outboard flap, and hence the aileron. The unacceptable flexibility of the outboard flap mechanism allows flutter to occur in extreme circumstances.

This amendment mandates Alert Service Bulletin ANMD-27-53, which requires modifications to the aircraft, but terminates the limitations imposed by earlier amendments.

Actions and Compliance

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

(1) Visually inspect the left-hand and right-hand ailerons for damage (i.e., distortion, bending, impact marks) and repair or replace any damaged aileron found following instructions obtained from the type-certificate holder (AeroSpace Technologies of Australia Pty Ltd) within the following time:

(i) *For Models N22B and N24A airplanes:* Inspect within 50 hours time-in-service (TIS) after December 23, 2003 (the effective date retained from AD 2003-22-13).

(ii) *For Model N22S airplanes:* Inspect within the next 10 hours TIS after November 8, 2006 (the effective date retained from AD 2006-21-12), or within 30 days after November 8, 2006 (the effective date retained from AD 2006-21-12), whichever occurs first.

(iii) *For all airplanes:* Repair or replace before further flight after the inspection where damage is found.

(2) Adjust the engine power lever actuated landing gear "up" aural warning microswitches, perform a ground test, and if deficiencies are detected during the ground test, make the necessary adjustments following Nomad Alert Service Bulletin ANMD-57-18, Rev 1, dated August 14, 2006, within the following time:

(i) *For Models N22B and N24A airplanes:* Within 50 hours TIS after December 23, 2003 (the effective date retained from AD 2003-22-13), unless already done following Nomad Alert Service Bulletin ANMD 57-18, dated December 19, 2002.

(ii) *For Model N22S airplanes:* Within the next 10 hours TIS after November 8, 2006 (the effective date retained from AD 2006-

21-12), or within 30 days after November 8, 2006 (the effective date retained from AD 2006-21-12), whichever occurs first.

(3) *For all airplanes:* Do the following within the next 10 hours TIS after the effective date of this AD or within 30 days after the effective date of this AD, whichever occurs first:

(i) Incorporate the maximum flap extension limitations specified in paragraph 2.D. of Nomad Alert Service Bulletin ANMD-57-18, Rev 1, dated August 14, 2006, into the Limitations section of the airplane flight manual (AFM). To show compliance with this paragraph of this AD, a copy of page 7 of Nomad Alert Service Bulletin ANMD-57-18, Rev 1, dated August 14, 2006, may be inserted into the Limitations section of the AFM. You may take "unless already done credit" for this subparagraph if done in accordance with AD 2006-21-12 and no further action is required to comply with this subparagraph.

(ii) Fabricate (using at least 1/8-inch letters) and install placards on the instrument panel within the pilot's clear view as specified in paragraph 2.E. of Nomad Alert Service Bulletin ANMD-57-18, Rev 1, dated August 14, 2006. You may take "unless already done credit" for this subparagraph if done in accordance with AD 2006-21-12 and no further action is required to comply with this subparagraph.

(iii) Incorporate the landing performance information specified in paragraph 2.F. of Nomad Alert Service Bulletin ANMD-57-18, Rev 1, dated August 14, 2006, into the Limitations section and the Performance section of the AFM.

(4) *For all airplanes:* Modify the outboard forward flap linkage (Modification N953) and modify the outboard aft flap (aileron) mass balance following Nomad Alert Service Bulletin ANMD-27-53, dated February 20, 2008, within the next 12 months after the effective date of this AD. Accomplishment of all of the actions specified in Nomad Alert Service Bulletin ANMD-27-53, dated February 20, 2008, terminates the limitations requirements and the placard requirements specified in paragraph (f)(3) of this AD.

FAA AD Differences

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

Other FAA AD Provisions

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

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Standards Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Doug Rudolph, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329-4059; fax: (816) 329-4090; e-mail: doug.rudolph@faa.gov. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from

a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

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

Related Information

(h) Refer to MCAI Civil Aviation Safety Authority of Australia, AD number AD/GAF-N22/69 Amdt 6, dated September 10, 2009, Nomad Alert Service Bulletin ANMD-27-53, dated February 20, 2008, and Nomad Alert Service Bulletin ANMD-57-18, Rev 1, dated August 14, 2006, for related information.

Issued in Kansas City, Missouri, on October 15, 2009.

Kim Smith,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. E9-25443 Filed 10-21-09; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2009-0951; Directorate Identifier 2007-SW-52-AD]

RIN 2120-AA64

Airworthiness Directives; Eurocopter France Model AS350B, BA, B1, B2, B3, C, D, D1, AS355E, F, F1, F2, and N Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for the specified Eurocopter France (Eurocopter) model helicopters. This proposed AD results from a mandatory continuing airworthiness information (MCAI) AD issued by the European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community. The AD MCAI states "EASA issued Airworthiness Directive (AD) 2006-0251 and its revisions following a case of total failure and a case of a crack discovered on the support shaft of the sliding door rear roller. Metallurgical and metallographic analyses revealed a nonconformity concerning the heat treatment of the material. Since then,

other cases of cracks and failures of the roller support shaft rear attach fitting had been reported. This condition, if not corrected, could lead to the loss of the sliding door in flight."

Separation of a sliding door in flight creates an unsafe condition because the door could come into contact with the rotor system. The proposed AD would require actions that are intended to address this unsafe condition.

DATES: We must receive comments on this proposed AD by November 23, 2009.

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

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Fax:* 202-493-2251.

- *Mail:* U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590.

- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

You may get the service information identified in this proposed AD from American Eurocopter Corporation, 2701 Forum Drive, Grand Prairie, Texas 75053-4005, telephone (972) 641-3460, fax (972) 641-3527.

Examining the 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 economic evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647-5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: DOT/FAA Southwest Region, Gary Roach, ASW-111, Aviation Safety Engineer, Rotorcraft Directorate, Regulations and Guidance Group, 2601 Meacham Blvd., Fort Worth, Texas 76137, telephone (817) 222-5130, fax (817) 222-5961.

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-2009-0951; Directorate Identifier 2007-SW-52-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 we receive about this proposed AD.

Discussion

EASA, which is the Technical Agent for the Member States of the European Community, has issued EASA AD No. 2007-0236, dated August 31, 2007, to correct an unsafe condition for specified Eurocopter model helicopters. The MCAI AD states that EASA issued AD 2006-0251 and its revisions following a case of total failure and a case of a crack discovered on the support shaft of the sliding door rear roller. Metallurgical and metallographic analyses revealed a nonconformity concerning the heat treatment of the material. Since then, other cases of cracks and failures of the roller support shaft rear attach fitting had been reported. EASA AD No. 2007-0236 supersedes EASA AD No. 2006-0251R2 but retains the requirements for repetitive inspections until replacement of current parts with improved parts. EASA AD No. 2007-0236 also prohibits installation of another roller support fitting part number (P/N) 350A25-1270-22 on any AS350 or AS355 helicopter. You may obtain further information by examining the MCAI AD and service information in the AD docket.

Related Service Information

On July 18, 2006, Eurocopter issued Alert Service Bulletin (ASB) No. 52.00.30 for modifying the AS350 series helicopters and ASB No. 52.00.23 for modifying the AS355 series helicopters. These ASBs contained modifications 073298 and 073308. The following day, Eurocopter issued ASB No. 05.00.45 for the AS355 model helicopters and No. 05.00.47 for the AS350 model helicopters, both dated July 19, 2006. Later, Eurocopter issued Revision 1 to ASB No. 52.00.23 for the AS355 model helicopters and No. 52.00.30 for the AS350 model helicopters, both dated June 29, 2007, to modify the sliding door medium roller and fitting. The actions described in the MCAI AD are intended to correct the same unsafe condition as that identified in the service information.

FAA's Evaluation and Unsafe Condition Determination

This product has been approved by the aviation authority of France and is approved for operation in the United States. Pursuant to our bilateral agreement with France, EASA, their technical agent, has notified us of the unsafe condition described in the MCAI AD. We are proposing this AD because we evaluated all information provided by EASA and determined an unsafe condition exists and is likely to exist or develop on other products of these same type designs.

Differences Between This AD and the MCAI AD

This AD differs from EASA AD No. 2007-0236 as follows:

- We use the word “inspect” to describe the actions required by a mechanic versus the word “check,” which is how we describe the actions allowed by a pilot.
- We refer to the compliance time as “hours time-in-service (TIS)” rather than “flying hours.”
- We do not require an operator to tell the manufacturer if a crack is found in the shaft.
- We are not including the Model L1, which is a military model helicopter; but we are including the Models 350C and D1 helicopters.

Costs of Compliance

We estimate that this proposed AD would affect about 725 products of U.S. registry. We also estimate that it would take about 4 work-hours per helicopter to inspect and modify the sliding doors. The average labor rate is \$80 per work-hour. Required parts would cost about \$7,000 per helicopter. Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be \$5,307,000.

Authority for This Rulemaking

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

We are issuing this rulemaking under the authority described in “Subtitle VII, Part A, Subpart III, Section 44701: General requirements.” Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority

because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

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

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

1. Is not a “significant regulatory action” under Executive Order 12866;
2. Is not a “significant rule” under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and
3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared an economic 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:

Eurocopter France: Docket No. FAA-2009-0951; Directorate Identifier 2007-SW-52-AD.

Comments Due Date

(a) We must receive comments by November 23, 2009.

Other Affected ADs

(b) None.

Applicability

(c) This AD applies to Eurocopter France Model AS350B, BA, B1, B2, B3, C, D, D1, AS355E, F, F1, F2, and N helicopters, with sliding door pre-MOD 073298 or pre-MOD 073308, installed, certificated in any category.

Reason

(d) The mandatory continuing airworthiness information (MCAI) AD states “EASA issued Airworthiness Directive (AD) 2006-0251 and its revisions following a case of total failure and a case of a crack discovered on the support shaft of the sliding door rear roller. Metallurgical and metallographic analyses revealed a nonconformity concerning the heat treatment of the material. Since then, other cases of cracks and failures of the roller support shaft rear attach fitting had been reported. This condition, if not corrected, could lead to the loss of the sliding door in flight.” Separation of a sliding door in flight creates an unsafe condition because the door could come into contact with the rotor system. This AD requires actions that are intended to address this unsafe condition.

Actions and Compliance

(e) Required as indicated.

(1) For a sliding door with less than 90 hours time-in-service (TIS), on or before accumulating a total of 110 hours TIS, unless already done, conduct the visual and dye penetrant inspections of the support shaft of the rear roller and the rear fitting (fitting) of the sliding door for a crack by reference to Figure 1 and by following the Operational Procedure, paragraph 2.B.1 and 2.B.2, of Eurocopter Alert Service Bulletin (ASB) No. 05.00.47 dated July 19, 2006, for the Model AS350 helicopters (ASB 05.00.47) or ASB No. 05.00.45 dated July 19, 2006, for the Model AS355 helicopters (ASB 05.00.45), except you are not required to contact the manufacturer.

(i) If no crack is found in the shaft or fitting, reinstall the shaft on the fitting, fit the spring pins, and plug the pin holes by following the Operational Procedure, paragraph 2.B.2. of ASB 05.00.47 or 05.00.45, whichever is appropriate for your model helicopter.

(ii) If you find a crack in the fitting, replace the fitting with an airworthy fitting before further flight.

(iii) If you find a crack in the shaft, replace the shaft with an airworthy shaft before further flight, by reference to Figure 1 and following paragraph 2.B.3. of ASB 05.00.47 or 05.00.45, whichever is appropriate for your model helicopter.

(2) For a sliding door with 90 or more hours TIS, within the next 20 hours TIS, unless already done, and thereafter at intervals not to exceed 110 hours TIS, conduct the visual and dye penetrant inspections of the support shaft of the rear roller and the fitting of the sliding door for a crack by reference to Figure 1 and by following the Operational Procedure, paragraph 2.B.1 and 2.B.2, of ASB 05.00.47 or ASB 05.00.45, whichever is appropriate for your model helicopter, except you are not required to contact the manufacturer.

(i) If no crack is found in the shaft and fitting, reinstall the shaft or fitting, fit the spring pins, and plug the pin holes by following the Operational Procedure, paragraph 2.B.2. of ASB 05.00.47 or 05.00.45, whichever is appropriate for your model helicopter.

(ii) If you find a crack in the fitting, replace the fitting with an airworthy fitting before further flight.

(iii) If you find a crack in the shaft, replace the shaft with an airworthy shaft before further flight by reference to Figure 1 and by following paragraph 2.B.3. of ASB 05.00.47 or 05.45, whichever is appropriate for your model helicopter.

(3) After the effective date of this AD, do not install any of the following parts on any helicopter:

(i) Left-hand sliding door, part number (P/N) 350A25-0030-00XX, 350A25-0120-00XX, and 350AMR-0227-0052;

(ii) Right-hand sliding door, P/N 350A25-0030-01XX, 350A25-0120-01XX, 350A25-0120-03XX, and 350AMR-0227-0051;

(iii) Rail roller pin, P/N 350A25-1275-20; and

(iv) Cast roller support fittings, P/N 350A25-1270-20 and P/N 350A25-1270-22.

Differences Between This AD and the MCAI AD

(f) This AD differs from EASA AD No. 2007-0236 as follows:

(1) We use the word "inspect" to describe the actions required by a mechanic versus the word "check," which is how we describe the actions allowed by a pilot.

(2) We refer to the compliance time as hours time-in-service (TIS) rather than flying hours.

(3) We do not require an operator to inform the manufacturer if a crack is found in the shaft as specified in the service information.

(4) We do not include the Model L1, which is a military model helicopter; but we are including the Models 350C and D1 helicopters.

Other Information

(g) Alternative Methods of Compliance (AMOCs): The Manager, Safety Management Group, Rotorcraft Directorate, ATTN: DOT FAA, Southwest Region, Gary Roach, ASW-111, Aviation Safety Engineer, Regulations and Guidance Group, 2601 Meacham Blvd., Fort Worth, Texas 76137, telephone (817) 222-5130, fax (817) 222-5961, has the authority to approve AMOCs for this AD, if requested, using the procedures found in 14 CFR 39.19.

Related Information

(h) MCAI EASA AD No. 2007-0236, dated August 31, 2007, contains related information.

Joint Aircraft System Component (JASC) Code

(i) JASC Code 5344: Fuselage Door Hinges.

Issued in Fort Worth, Texas, on October 8, 2009.

Larry M. Kelly,

Acting Manager, Rotorcraft Directorate,
Aircraft Certification Service.

[FR Doc. E9-25440 Filed 10-21-09; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Parts 131 and 292

[Docket No. RM09-23-000]

Revisions to Form, Procedures, and Criteria for Certification of Qualifying Facility Status for a Small Power Production or Cogeneration Facility

October 15, 2009.

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Notice of proposed rulemaking.

SUMMARY: In this Notice of Proposed Rulemaking, the Federal Energy Regulatory Commission (Commission) proposes to revise its regulations, which currently provide the FERC Form No. 556 (Form 556) that is used in the certification of qualifying status for an existing or proposed small power production or cogeneration facility. The Commission proposes to revise its regulations to remove the contents of the Form No. 556 from the regulations, and, in their place, to provide that an applicant seeking to certify qualifying facility (QF) status of a small power production or cogeneration facility must complete, and electronically file, the Form No. 556 that is in effect at the time of filing. We propose to revise and reformat the Form No. 556 to clarify the content of the form and to take advantage of newer technologies that will reduce both the filing burden for applicants and the processing burden for the Commission. We also propose to exempt generating facilities with net power production capacities of 1 MW or less from the QF certification requirement, and to codify the Commission's authority to waive the QF certification requirement for good cause. Finally, we propose to clarify, simplify or correct certain sections of the regulations.

DATES: Comments must be filed on or before December 21, 2009.

ADDRESSES: You may submit comments, identified by Docket No. RM09-23-000, by one of the following methods:

Agency Web site: <http://www.ferc.gov>. Follow the instructions for submitting comments via the eFiling link found in the Comment Procedures Section of the preamble.

Mail: Commenters unable to file comments electronically must mail or hand deliver an original and 14 copies of their comments to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street, NE.,

Washington, DC 20426. Please refer to the Comment Procedures Section of the preamble for additional information on how to file paper comments.

FOR FURTHER INFORMATION CONTACT:

Tom Dautel (Technical Information), Division of Economic and Technical Analysis, Office of Energy Policy and Innovation, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, Telephone: (202) 502-6196, E-mail: thomas.dautel@ferc.gov.

Paul Singh (Technical Information), Division of Tariffs and Market Development—West, Office of Energy Market Regulation, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, Telephone: (202) 502-8576, E-mail: paul.singh@ferc.gov.

S.L. Higginbottom (Legal Information), Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, Telephone: (202) 502-8561, E-mail: samuel.higginbottom@ferc.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

1. The Commission proposes to revise § 131.80 of its regulations,¹ which currently sets forth the FERC Form No. 556 (Form 556) that is used in the certification of qualifying status for an existing or proposed small power production or cogeneration facility. Section 131.80 now contains Form No. 556 and general instructions for completing the form. The Commission proposes to revise § 131.80 of its regulations to remove the contents of the Form No. 556 and, in their place, provide that an applicant seeking to certify qualifying facility (QF) status of a small power production or cogeneration facility must complete and file the Form No. 556 that is in effect at the time of filing, which will be made available for download from the Commission's QF Web site.² The Commission also proposes to require that the Form No. 556 be submitted to the Commission electronically.

2. The Commission proposes to revise and reformat the Form No. 556 to clarify the content of the form and to take advantage of newer technologies that will reduce both the filing burden for applicants and the processing burden for the Commission.

3. The Commission also proposes revisions to the procedures, standards and criteria for QF status provided in Part 292 of its regulations to accomplish

¹ 18 CFR 131.80.

² <http://www.ferc.gov/QF>.

the following: (1) Exemption of generating facilities with net power production capacities of 1 MW or less from the QF certification requirement; (2) codification of the Commission's authority to waive the QF certification requirement for good cause; (3) extension to all applicants for the QF certification requirement (currently applicable only to applicants for self certification of QF status) to serve a copy of a filed Form No. 556 on the affected utilities and state regulatory authorities; (4) elimination of the requirement for applicants to provide a draft notice suitable for publication in the **Federal Register**; and (5) clarification, simplification or correction of certain sections of the regulations.³

4. Finally, the Commission proposes a change to the exemption of QFs from the Federal Power Act,⁴ and to the exemption of QFs from the Public Utility Holding Company Act of 2005 (PUHCA) and certain State laws and regulations⁵ to make clear that certain small power production facilities that satisfy the criteria of section 3(17)(E) of the Federal Power Act qualify for those exemptions.

5. The Commission is proposing the revisions described above with the following goals: (1) Making the Form No. 556 easier and less time consuming to complete and submit; (2) decreasing opportunities for confusion and error in completing the form; (3) improving consistency and quality of the data collected by the form; (4) decreasing Commission resources dedicated to managing errors and omissions in submitted forms; and (5) clarifying and correcting the regulations governing the requirements for obtaining and maintaining QF status.

6. The proposed revisions to the Form No. 556 and the procedures for filing the Form No. 556 are informed by the Commission's experience both with administering the Form No. 556 and with new technologies for electronic data collection that have become available since the Form No. 556 was first established by Order No. 575 in 1995.⁶ We believe that the proposed changes will increase the effectiveness of the Commission's policies encouraging cogeneration and small power production, as required by

section 210 of the Public Utility Regulatory Policies Act of 1978 (PURPA).

II. Background

7. When the Commission first implemented section 201 of PURPA, it provided two paths to QF status: self-certification and Commission certification.⁷ The procedures for self-certification are contained in § 292.207(a) of the Commission's regulations.⁸ When a small power production facility or cogeneration facility self-certifies (or self-recertifies),⁹ it certifies that it satisfies the requirements for QF status. The Commission does not formally review the self-certification. Instead, the self-certification is assigned a docket number, and Commission staff looks at the filing to determine that the self-certifier has provided the information required by the regulations.

8. Self-certification was an essential part of the Commission's implementation of PURPA, and was intended, in part, to make the certification process quick and not unduly burdensome. Thus, when the Commission first implemented section 201 of PURPA in Order No. 70,¹⁰ the Commission rejected a proposal to adopt a case-by-case Commission certification requirement for all QFs, but instead provided that facilities that met the requirements for QF status need only furnish notice to the Commission of QF status.¹¹ This notice (the self-certification) was purely for informational purposes and to help the Commission monitor the market penetration of QFs. QF status, however, was established by meeting the requirements for such status and did not

depend on the filing. Indeed, the Commission noted that QFs and purchasing utilities could agree that a generation facility met the requirements for QF status, and the facility would qualify for the benefits of PURPA without making any filing with the Commission.

9. The Commission recognized, however, that the self-certification process would not always satisfy all those interested in a particular facility's status. Accordingly, the Commission also established, in § 292.207(b) of the regulations,¹² the "optional procedure" for QF status. Under the optional procedure, an entity may file an application for a determination by the Commission that a facility meets the requirements for QF status. Such an application requires a filing fee.¹³ After receiving an application for Commission certification and the required fee, the Commission assigns the filing a docket number and notices the filing in the **Federal Register**, providing an opportunity for interventions and protests. The Commission's regulations provide that it will act on an application within 90 days of the filing (or of its supplement or amendment). The process gives those that need assurance of a facility's QF status (or lack of such status) a Commission order certifying (or denying) QF status. This optional procedure is commonly known as an application for Commission certification. In its original regulations, the Commission also provided that, once a facility was certified by the Commission, its qualifying status could be revoked by the Commission, upon the Commission's own motion, or upon the motion of any person.¹⁴ This combination of encouraging self-certifications, while providing for both Commission-certification and an opportunity to seek revocation of QF status, would assure, the Commission believed, that only those generation facilities that meet the criteria for QF status would receive and retain that status.

⁷ There is no fee for a self-certification; there is, however, a fee for Commission certification. 18 CFR 381.505. The Commission will not process an application for Commission certification without receipt of the applicable fee.

⁸ 18 CFR 292.207(a).

⁹ Because recertification is a type of certification, policies applicable to self-certification and application for Commission certification also apply to self-recertification and application for Commission recertification.

¹⁰ *Small Power Production and Cogeneration Facilities—Qualifying Status*, Order No. 70, FERC Stats. & Regs., Regulations Preambles 1977–1981 ¶ 30,134 (1980), *order on reh'g*, Order Nos. 69–A and 70–A, FERC Stats. & Regs., Regulations Preambles 1977–1981 ¶ 30,160 (1980), *aff'd in part and vacated in part*, *American Electric Power Service Corp. v. FERC*, 675 F.2d 1226 (D.C. Cir. 1982), *rev'd in part*, *American Paper Institute, Inc. v. American Electric Power Service Corp.*, 461 U.S. 402 (1983).

¹¹ Order No. 70, FERC Stats. & Regs. ¶ 30,134 at 30,954. As discussed below, the Commission, in 2005, added a requirement that a cogeneration facility or small power production facility either self-certify or receive Commission certification to have QF status. See 18 CFR 292.203(a)(3), (b)(2).

¹² 18 CFR 292.207(b).

¹³ 18 CFR 381.505.

¹⁴ See 18 CFR 292.207(d)(ii). A similar opportunity for the Commission to revoke the QF status of a self-certified facility on the Commission's own motion, or on the motion of another party, was not expressly provided in the regulations; the Commission, however, allowed others to seek the revocation of a self-certified QF by filing a petition for declaratory order. In Order No. 671, *infra* note 18, the right to file a motion seeking revocation of a self-certification was added to the Commission's regulations. A motion seeking revocation requires a filing fee as a declaratory order. *Chugach Electric Association, Inc.*, 121 FERC ¶ 61,287, at P 51–54 (2007). The filing fee for a declaratory order is provided in 18 CFR 381.302.

³ 18 CFR Part 292.

⁴ 18 CFR 292.601.

⁵ 18 CFR 292.602.

⁶ *Streamlining of Regulations Pertaining to Parts II and III of the Federal Power Act and the Public Utility Regulatory Policies Act of 1978*, Order No. 575, 60 FR 4831 (Jan. 25, 1995), FERC Stats. & Regs. ¶ 31,014, *order on reh'g*, Order No. 575–A, 71 FERC ¶ 61,121 (1995).

10. As noted above, the Commission, when it first enacted its regulations, had hoped that self-certifications would be the primary means for obtaining QF status, but recognized that there would be instances in which a Commission ruling on QF status would be desirable. While the Commission later, in Order No. 575, required QFs to provide more detailed information about self-certifying QFs, in Form No. 556, the Commission continued to encourage self-certification, but also recognized that there would be reasons that a QF may want or need Commission certification (including the requirement of some lenders, electric utilities, or state regulators that a generator seeking QF status and the benefits of PURPA be Commission-certified). The Commission thus sought to make the self-certification process more informative about the nature of the self-certified QFs while keeping the process relatively simple. The Commission stated the following:

The Commission continues to believe that self-certification should be retained as an option; it is unnecessary to conduct a full review of each facility, even in instances where outside lenders and investors will be involved. However, in consideration of the various comments, and in recognition of the various other clarifications being made in this final rule, the Commission will not adopt the proposed affidavit requirement. Instead, the Commission will modify the self-certification process to: (a) incorporate the Form 556 information requirement that the Commission is also adopting for applications for Commission certification; and (b) require that cogenerators and small power producers provide copies of the notice of self-certification to each affected state commission and to each affected electric utility. The self-certifying cogenerator or small power producer must also specify the utility services that it intends to request (see item 3b of Form 556).¹⁵

11. Following the enactment of the Energy Policy Act of 2005 (EPA 2005), which imposed new requirements for QF status for “new” cogeneration facilities,¹⁶ the Commission issued Order No. 671,¹⁷ which implemented

those new requirements. As part of that implementation, for the first time, notices of self-certifications for new cogeneration facilities were required to be published in the **Federal Register**; self-certifications, other than for new cogeneration facilities, are not published in the **Federal Register**. In addition, as noted above, for the first time, the Commission required the filing of a notice of self-certification or an application for Commission certification as a requirement for QF status.¹⁸

III. Proposed Revisions to Regulations

A. Revisions to 18 CFR 131.80

12. Currently, § 131.80 of the Commission regulations contains the text of Form No. 556 as well as instructions on how to complete the form. We propose that § 131.80 of the Commission’s regulations will no longer contain Form No. 556. In place of the current language, we propose to require in § 131.80(a) that any person seeking to certify a facility as a QF must complete and file the Form No. 556 then in effect and in accordance with the instructions then incorporated in that form.

13. Revising § 131.80 as proposed will make it easier to clarify and correct the form, should such changes prove necessary or appropriate in the future. Future changes to the form would be reviewed by the Office of Management and Budget following a solicitation of comments from the public on proposed changes, but would not require a formal rulemaking. This treatment is consistent with how a number of other Commission information collections are managed, including FERC Form Nos. 1, 1–F, 3–Q, 60, 80, 423, 714, and 715, as well as the FERC Form No. 580 Interrogatory.¹⁹

14. We are also proposing to require, through proposed § 131.80(c), that applicants submit their QF applications (whether initial certifications or recertifications, and whether self-certifications or applications for Commission certification) electronically via the Commission’s eFiling website. We make this proposal for several reasons. First, for most applicants, the electronic filing process will be faster, easier, less costly and less resource-intensive than hardcopy filing. An applicant filing electronically will receive an acknowledgement that the Commission has received their application and a docket number for their submittal much more quickly than they would by filing in hardcopy format. Also, electronic filing will allow

the Commission to electronically process QF applications, dramatically reducing required staff resources and human error, and allowing the Commission to identify patterns of reporting errors and noncompliance that would be difficult to detect through manual processing. Finally, electronic filing of QF applications would facilitate the compilation of QF data that could be made available to the public. Each year Commission staff field a number of requests for QF certification data from private organizations, researchers and other government agencies. Requiring applicants to file in electronic format would make it possible to respond to many more such requests, and/or to publish compiled QF data on the Commission’s website.

15. While electronic filing of QF certifications has many benefits, we recognize that some of the parties submitting applications for certification of QF status are small entities that consider the cost of legal representation to be burdensome and/or that lack access to the computer facilities necessary to make an electronic filing.

16. To address this concern, we propose to amend § 292.203 to exempt the smallest applicants, those with a net power production capacity less than or equal to 1 MW, from the requirement to make any filing with the Commission in order to be a QF. Facilities larger than 1 MW represent a significant departure from residential power generation, and we would expect entities certifying such facilities to have access to the legal representation and the computer facilities needed to electronically file a Form No. 556. We seek comments on this proposal, and, in particular, on whether a 1 MW threshold is the appropriate threshold. We note that until the effective date of Order No. 671, no filing, either of a self-certification or an application for Commission certification, was needed for QF status. In instituting the filing requirement for QF status, the Commission, among other things, explained that requiring a filing would help ensure that a “new” cogeneration facility would not be able to claim QF status without making a filing; the Commission believed that the Congressional mandate to tighten the standards for cogeneration facilities required that a filing, either a self-certification or an application for Commission certification, be made by an entity claiming QF status.²⁰ While, as discussed above, the data submitted on Form No. 556 are valuable, there may not be as compelling reasons for

¹⁵ Order No. 575, FERC Stats. & Regs. ¶ 31,014 at 31,275.

¹⁶ A “new” cogeneration facility is defined as any cogeneration facility that was either not a qualifying cogeneration facility on or before August 8, 2005, or that had not filed a notice of self-certification, self-recertification or an application for Commission certification or Commission recertification as a qualifying cogeneration facility prior to February 2, 2006. 16 U.S.C. 824a–3(n)(2)(B); 18 CFR 292.205(d).

¹⁷ *Revised Regulations Governing Small Power Production and Cogeneration Facilities*, Order No. 671, 71 FR 7852 (Feb. 2, 2006), FERC Stats. & Regs. ¶ 31,203 (2006), *order on reh’g*, Order No. 671–A, 71 FR 30585 (May 22, 2006), FERC Stats. & Regs. ¶ 31,219 (2006).

¹⁸ See 18 CFR 292.203(a)(3), (b)(2).

¹⁹ 18 CFR 366.23.

²⁰ Order No. 671, FERC Stats. & Regs. ¶ 31,203 at P 81.

facilities that are very small, such as solar generation facilities installed at residences or other relatively small electric consumers such as retail stores, hospitals, or schools, to make filings with the Commission for QF status.

17. Alternatively, we could maintain a hardcopy filing requirement for small facilities instead of exempting small facilities from any certification requirement; however, such a policy would add considerably to the complexity of the Commission's regulations. The very limited benefit of such a policy does not seem to justify this added complexity or the burden on the affected parties.

B. Revisions to 18 CFR 292.203

18. Section 292.203 of our regulations²¹ lists the general requirements for QF status. For a qualifying small power production facility, those requirements currently state that the facility must meet the maximum size criteria specified in § 292.204(a), meet the fuel use criteria specified in § 292.204(b), and must have filed a notice of self-certification or an application for Commission certification that has been granted. For a qualifying cogeneration facility, those requirements currently state that the facility must meet any applicable operating and efficiency standards provided in § 292.205(a) and (b), and that the facility must have filed a notice of self-certification or an application for Commission certification that has been granted.

19. We propose to correct an inadvertent error in § 292.203(b)(1) of our regulations.²² Order No. 671 implemented additional technical requirements for certain cogeneration facilities in § 292.205(d), but § 292.203(b)(1) was not updated to reflect that a facility must comply with these new requirements (if applicable) in order to be a qualifying cogeneration facility. We propose to add the reference to § 292.205(d) in § 292.203(b). Because the technical requirements of § 292.205(d) are not "operating and efficiency standards," we propose to amend § 292.203(b) to delete the phrase "operating and efficiency standards" and to replace it with the phrase "standards and criteria."

20. Finally, as mentioned above, we seek comments on whether to add a § 292.203(d) which would exempt certain very small facilities from the requirement to make a filing for qualifying status and would make explicit the Commission's authority to

grant waiver of the filing requirement upon petition where good cause is shown.²³ As discussed above, certain very small facilities may find the filing requirement for obtaining QF status to be unduly burdensome. On the other hand, there is value to the data received in a self-certification, the self-certification process has been designed to be and is relatively easy, and we intend to make it easier with the adoption of an easier-to-use Form No. 556.

C. Revisions to 18 CFR 292.204

21. Section 3(17)(E) of the Federal Power Act provides that an "eligible solar, wind, waste or geothermal facility" is a facility which produces electric energy solely by the use, as a primary energy source, of solar energy, wind energy, waste resources or geothermal resources, but only if such facility meets certain criteria for dates of certification and construction. Section 3(17)(A) of the Federal Power Act provides that any eligible solar, wind, waste, or geothermal facility is a small power production facility, regardless of its size. The Commission implemented these sections of the Federal Power Act in § 292.204(a), including the statement that there are no size limitations for "eligible" solar, wind or waste facilities,²⁴ as defined by section 3(17)(E) of the Federal Power Act. The regulation then states that, for "a non-eligible facility," the size limitation for a qualifying small power production facility is 80 MW.

22. The wording of § 292.204(a) has created confusion for many applicants. Applicants not familiar with section 3(17)(A) or (E) of the Federal Power Act frequently confuse the statutory concept of "eligibility" with more general questions of whether their facility is eligible for QF status. They often assume that an "eligible facility" is any facility that is eligible for qualifying status. In an attempt to reduce such confusion, we propose to revise § 292.204(a) to be more clear while achieving the same regulatory outcome as the current § 292.204(a); the proposed revision avoids using the term "eligible."

D. Revisions to 18 CFR 292.205

23. The text of § 292.205(d) of the Commission's regulations²⁵ contains an

error in the description of the new cogeneration facilities that are subject to the requirements of §§ 292.205(d)(1) and (2). Section 292.205(d) provides that the following facilities are subject to these requirements:

Any cogeneration facility that was either not certified as a qualifying cogeneration facility on or before August 8, 2005, or that had not filed a notice of self-certification, self-recertification or an application for Commission certification or Commission recertification as a qualifying cogeneration facility under § 292.207 of this chapter prior to February 2, 2006, and which is seeking to sell electric energy pursuant to section 210 of the Public Utility Regulatory Policies Act of 1978, 16 U.S.C. 824a-1.^[26]

24. From this language, the criteria for QF status include whether or not a cogeneration facility was "certified as" a qualifying cogeneration facility by August 8, 2005.²⁷ However, the text of section 210(n)(2) of PURPA states that the Commission's prior cogeneration requirements shall continue to apply to any facility that "was a qualifying cogeneration facility on [August 8, 2005]." ²⁸ Furthermore, at the time of enactment of EPAct 2005, the Commission's regulations did not require that a facility that complied with the requirements for QF status be certified in order to be a QF.²⁹ As such, there were many facilities that were QFs on August 8, 2005, even though they were not certified as QFs by that date. To correct this error, we propose to strike the words "certified as" from the first sentence of § 292.205(d).

25. Section 210(n)(2) of PURPA also states that the Commission's prior cogeneration requirements will continue to apply to any facility that "had filed with the Commission a notice of self-certification, self recertification or an application for Commission certification under 18 CFR 292.207 prior to [February 2, 2006]." ³⁰ The Commission implemented this provision in § 292.205(d) by not applying the new cogeneration requirements to any cogeneration facility that had filed "a notice of self-certification, self-recertification or an application for Commission certification or Commission recertification as a qualifying cogeneration facility under § 292.207 of this chapter prior to February 2, 2006." Because any facility

²⁶ *Id.* (emphasis added).

²⁷ The significance of August 8, 2005 is that it is the date on which the Energy Policy Act of 2005 was signed into law.

²⁸ 16 U.S.C. 824a-3(n)(2)(A) (emphasis added).

²⁹ See *Revised Regulations Governing Small Power Production and Cogeneration Facilities*, Order No. 671, 71 FR 7852 at P 81 (Feb. 2, 2006), FERC Stats. & Regs. ¶ 31,203, at P 81 (2006).

³⁰ 16 U.S.C. 824a-3(n)(2)(B).

²¹ 18 CFR 292.203.

²² 18 CFR 292.203(b)(1).

²³ See *Ashland Windfarm, LLC*, 124 FERC ¶ 61,068 (2008) (Commission granted waiver of the filing requirement for QF status).

²⁴ "Geothermal" was inadvertently omitted when the regulation was written. The change we are proposing obviates the need to correct this omission.

²⁵ 18 CFR 292.205(d).

that had recertified (either by self-recertification or application for Commission recertification) prior to February 2, 2006 must necessarily have made its original certification prior to February 2, 2006, the inclusion of “self-recertification” and “application for Commission recertification” in this provision is unnecessary. We propose to simplify § 292.205(d) to state that the new cogeneration requirements will not apply to any facility that had filed “a notice of self-certification or an application for Commission certification as a qualifying cogeneration facility under § 292.207 of this chapter prior to February 2, 2006.” This proposed revision would achieve the same regulatory result while decreasing the complexity of the regulatory text, and thus the opportunities for confusion.

E. Revisions to 18 CFR 292.207

1. Elimination of Pre-Authorized Commission Recertification

26. We propose to eliminate the procedure for pre-authorized Commission recertification contained in § 292.207(a)(2).³¹ That procedure was established to give applicants for facilities that have been certified under the procedures for Commission certification in § 292.207(b) a list of insubstantial alterations and modifications that would not result in the revocation of QF status previously granted by the Commission. Section 292.207(a)(2)(ii) also requires those making the changes listed in § 292.207(a)(2)(i) to notify the Commission and each affected utility and State regulatory authority of each such change.

27. The pre-authorized Commission recertification process does not currently require the use of Form No. 556, and historically the very few applicants that have filed pre-authorized Commission recertifications have done so in the form of a letter describing the changes to their facilities. In this rulemaking, we are implementing procedures to require that self-certifications or applications for Commission certification be made through the electronic submission of a Form No. 556. Removing the pre-authorized recertification option ensures that all QF certification filings will be made electronically using Form No. 556. We could opt to revise the procedure for the pre-authorized Commission recertification to require such filings to be made electronically using a Form No. 556, but such a revised procedure would be essentially

identical to the procedure for self-certification. Having such a duplicative procedure appears unjustified, particularly given the increase in complexity to the Form No. 556 and the Commission’s regulations that would result.

28. Furthermore, we note that the types of changes listed in § 292.207(a)(2)(i) may be somewhat misleading, as a strict reading of that list may imply that almost any change to a QF, no matter how small, would require notice to the Commission and to the affected utilities and State regulatory authorities. In reality, changes falling below a certain level of importance are not significant enough to justify the burden on the applicant of the recertification requirement.

2. Elimination of Procedures for Referring to Information From Previous Certifications

29. Section 292.207(a)(1)(iii) provides that subsequent notices of self-recertification for the same facility may reference prior notices or prior Commission certifications, and need only refer to changes which have occurred with respect to the facility since the prior notice or the prior Commission certification. We propose to delete this provision, and, as a result, to change the Commission’s policy so that applicants are required to provide all of the information for their facility in each Form No. 556 they submit with a self-recertification or an application for Commission recertification. We believe this proposed change will result in greater transparency. During the processing of routine QF petitions and periodic compliance reviews of self-certifications, the Commission frequently finds that the original certification data for some facilities (particularly facilities originally certified in the 1980s) can be difficult to obtain. And requiring the provision of full data in a recertification would be a small, one-time burden for applicants, because applicants may, after their first recertification subsequent to a Final Rule implementing this proposal, simply download their previous electronically-filed Form No. 556 from eLibrary and update the relevant responses to generate their new Form No. 556. Given the significant benefit and the small, one-time burden, deletion of § 292.207(a)(1)(iii) appears appropriate.

3. Elimination of Requirement to Provide a Draft Notice Suitable for Publication in the Federal Register

30. Section 292.207(a)(1)(iv) of our regulations³² currently requires that notices of self-certifications and self-recertifications for new cogeneration facilities be published in the **Federal Register**. Similarly, § 292.207(b)(4) of our regulations³³ requires that notices of applications for Commission certification or recertification be published in the **Federal Register**. For these applications that require publication of notices in the **Federal Register**, §§ 292.207(a)(1)(iv) and (b)(4) require that applicants provide with their filing a draft notice suitable for publication in the **Federal Register** on electronic media.

31. We propose to continue to publish notices self-certification and self-recertification for new cogeneration facilities and applications for Commission certification and recertification in the **Federal Register**, and we include that requirement in the proposed § 292.207(c). However, we propose to delete §§ 292.207(a)(1)(iv) and (b)(4) in order to eliminate the requirement that applicants for those types of filings provide a draft notice suitable for publication in the **Federal Register**. We have found that there is a significant amount of confusion among many QF applicants—particularly smaller applicants—about exactly what a **Federal Register** notice is, and how to provide a draft of such a notice on electronic media. Furthermore, because under the proposed changes to § 131.80 applicants would file their Forms 556 electronically, the Commission can automatically generate **Federal Register** notices directly from the Form No. 556 data, without requiring a draft notice submitted by the applicant. We expect this proposed amendment will result in a decrease in the burden to small QF applicants.

4. Requirement to Serve a Copy of a Form No. 556 on Affected Utilities and State Commissions

32. Currently applicants for self-certification are required to serve a copy of their QF self-certification filings on each electric utility with which they expect to interconnect, transmit or sell electric energy to, or purchase supplementary, standby, back-up and maintenance power from, and the State regulatory authority of each state where the facilities and each affected electric

³¹ 18 CFR 292.207(a)(2).

³² 18 CFR 292.207(a)(1)(iv).

³³ 18 CFR 292.207(b)(4).

utility is located.³⁴ No such requirement currently exists for applications for Commission certification.

33. We propose to amend the regulations to require that any applicant filing a self-certification, self-recertification, application for Commission certification or application for Commission recertification must serve a copy of its filing on each affected electric utility and State regulatory authority. Specifically, we propose to make the following revisions: (1) Delete § 292.207(a)(1)(ii); (2) rename § 292.207(c) "Notice requirements" instead of the current "Notice requirements for facilities of 500 kW or more"; (3) insert § 292.207(c)(1) before the current first paragraph in § 292.207(c), that would establish that any applicant for self-certification, self-recertification, Commission certification or Commission recertification must serve on each affected utility and state regulatory authority a copy of its filing; and (4) revise the existing text of § 292.207(c), which will become § 292.207(c)(2), requiring facilities of 500 kW or more to provide that an electric utility is not required to purchase electric energy from a facility with a net power production capacity of 500 kW or more until 90 days after the facility meets the notice requirements in § 292.207(c)(1).

5. Other Proposed Changes

34. We propose to remove reference to "pre-authorized Commission recertification" in the title of § 292.207(a) and in the body text of § 292.207(d)(1)(i). We also propose to delete the current § 292.207(a)(1), and to replace it, in § 292.207(a), with a procedure for self-certification that incorporates clear reference to proposed § 131.80 and to the notice requirements in § 292.207(c).

F. Revisions to 18 CFR 292.601

35. We propose to amend § 292.601(a) of our regulations³⁵ to make clear the exemption from the specified Federal Power Act sections is applicable to any facility that meets the definition of an "eligible solar, wind, waste or geothermal facility" under section 3(17)(E) of the Federal Power Act. Section 4 of the Solar, Wind, Waste, and Geothermal Power Production Incentives Act of 1990 (Incentives Act)³⁶ provides that "eligible facilities" shall not be subject to the size limitations contained in § 292.601(b) of

the Commission's regulations, unless the Commission otherwise specifies. The Commission has found that the size limitation for eligibility for the exemptions contained in §§ 292.601 and 292.602, otherwise applicable to other small power production facilities, does not apply to "eligible facilities."³⁷ We propose to amend § 292.601(a) to make that clear.³⁸

G. Revisions to 18 CFR 292.602

36. We propose to amend § 292.602(c)(1) to clarify that it is only the QFs described in paragraph (a) of that section that may take advantage of the exemptions provided in § 292.602, and to correct a typographical error. Finally, we propose to correct a typographical error in the title of § 292.602.

IV. Proposed Revisions to the Form No. 556

A. General

37. We propose to make a number of changes to the content and organization of the Form No. 556. A proposed revised Form No. 556 is included as Attachment A to this document, and will be available for download from the Commission's QF Web site.³⁹ As discussed above, we are not proposing to include the content of the Form No. 556 in the Commission's regulations, however, the changed Form No. 556, once approved, will become "the Form No. 556 then in effect" for purposes of the proposed § 131.80. We are therefore giving notice of our proposed changes to Form No. 556, which after receiving and considering comments on those changes, we will submit for OMB approval pursuant to the provisions of the Paperwork Reduction Act of 1995.⁴⁰

38. In addition to the structure of the proposed Form No. 556, we propose to include (in the Final Rule version of the form) data controls, automatic calculations, error handling and other programmatic features to assist applicants and maintain data quality. We request comment on any specific

features that interested persons would find useful, and that should be included in the form.

39. Most of the proposed changes to the Form No. 556 are intended to make use of new electronic data structuring. While, in most cases, we propose to collect the same data that is currently collected in the Form No. 556, the new form will allow the Commission to more efficiently administer the QF program. Commission staff spends a significant amount of time working with applicants that either misunderstand the current form, pay insufficient attention to the informational requirements on the current form, or both. By making Form No. 556 easier to understand, we will make the submission of Form No. 556 less burdensome to applicants.

40. Our experience has been that the open-ended nature of the current Form No. 556 data collection—where applicants are able to type any answer or no answer in response to an item—often results in applicants incorrectly answering or skipping items or portions of items that they mistakenly feel do not apply to them. Improved instructions, the use of a greater number of questions which are individually narrower in scope, and the use of certain electronic data controls and validation options, such as checkboxes and data entry fields that only accept data formatted in the appropriate way, are proposed to minimize these problems.

41. We seek comments on any aspect of the proposed form. While many of the changes to the form are self-explanatory, we discuss the more significant changes below.

B. Name of Form

42. In Order No. 575, the Commission adopted San Diego Gas and Electric Company's suggestion to title the Form No. 556 to make clear that it applies to proposed as well as to existing facilities.⁴¹ We are not proposing to change the applicability of the form to proposed and existing facilities; however, as part of our attempt to make the Form No. 556 as simple and clear as possible, we propose to shorten the name of the form to "Certification of Qualifying Facility (QF) Status for a Small Power Production or Cogeneration Facility."

C. Geographic Coordinates

43. Over the years we have received a number of inquiries from the public seeking certain information about QFs. Many of these inquiries were from academics, research organizations or

⁴¹ Order No. 575, 60 FR 4831 (Jan. 13, 1995), FERC Stats. & Regs. ¶ 31,014, at 31,282 and 31,285.

³⁴ 18 CFR 292.207(a)(ii).

³⁵ 18 CFR 292.601(a).

³⁶ Public Law 101-575, 104 Stat. 2834 (1990), as amended by Public Law 102-46, 105 Stat. 249 (1991).

³⁷ *Cambria Cogen Co.*, 53 FERC ¶ 61,459, at 62,619 (1990).

³⁸ Because 18 CFR 292.602(a) states that the exemption from PUHCA and State laws and regulations provided in that section applies to any QF described in 18 CFR 292.601(a), and because the QFs described by 18 CFR 292.601(a) include all QFs other than those described by 18 CFR 292.601(b), the Incentives Act's exemption of "eligible facilities" from the size limitation contained in 18 CFR 292.601(b) has the effect of making such facilities also eligible for the exemptions from PUHCA and State laws and regulations in 18 CFR 292.602.

³⁹ <http://www.ferc.gov/QF>. The proposed revised Form No. 556 will not be attached to the Microsoft Word version of this document.

⁴⁰ 44 U.S.C. 3507(d).

other government entities performing studies of the effectiveness of PURPA and the Commission's regulations implementing PURPA. Often such inquiries have involved the dates that applications for different types of QFs were filed (particularly relative to certain changes in policies) and the locations of the QFs. Currently, location information is collected only through the street address of the facility, even though some facilities in rural or wilderness areas do not have a street address.

44. We believe it may be useful to researchers (as well as the public in general, and affected electric utilities and State regulatory authorities in particular) to have specific locational data for QFs, even for facilities that do not have street addresses. In addition to having value for researchers, such specific locational data would also provide a transparent means of determining compliance with the size requirement for small power production facilities, which is based in part on the distance between adjacent generating facilities. As such, we propose to include a new line 3c that will require applicants for facilities without a street address to provide the geographic coordinates (latitude and longitude) of their facilities. The text of the proposed line 3c directs applicants to the Geographic Coordinates section of the instructions on page 4 which discusses several different ways through which applicants might obtain the geographic coordinates of their facilities: Through certain free online map services (with links available through the Commission's QF Web site); a GPS device; Google Earth; a property survey; various engineering or construction drawings; a property deed; or a municipal or county map showing property lines. Applicants are directed in line 3c to provide their geographic coordinates to three decimal places, and are given a simple formula for how to convert degrees, minutes and seconds to decimal degrees. We solicit comments on the submission of locational information for facilities that do not have a street address.

D. Ownership

45. In Order No. 671, the Commission eliminated the limitation on electric utility and electric utility holding company ownership of QFs, but maintained the requirement that applicants provide ownership information in the Form No. 556.⁴²

⁴² Revised Regulations Governing Small Power Production and Cogeneration Facilities, Order No. 671, 71 FR 7852 (Feb. 2, 2006), FERC Stats. & Regs.

46. The wording of item 1c of the current Form No. 556 has proven confusing with respect to the collection of ownership information. In particular, item 1c does not specify the amount of equity interest in the facility above which the applicant is required to identify the owner. For facilities with many owners, this can prove burdensome, particularly if the ownership changes frequently.

47. Experience has also shown that the current wording of item 1c proves confusing to applicants with respect to which types of owners (direct or upstream) they are supposed to identify.

48. We propose to clarify both the level of ownership above which applicants are required to identify owners, and which information must be provided for direct and upstream owners. First, while maintaining the current requirement that applicants indicate the percentage of direct ownership held by any electric utility⁴³ or holding company,⁴⁴ we propose to clarify in line 5a of the proposed Form No. 556 that applicants need only provide information for direct owners that hold at least 10 percent equity interest in the facility.⁴⁵ Second, we propose to require in line 5b that applicants identify all upstream owners that both (1) hold at least a 10 percent equity interest in the facility and (2) are electric utilities or holding companies.

49. We seek comments on these changes to the ownership requirement. In particular, we seek comment on whether the 10 percent equity interest threshold is the proper threshold.

E. Fuel Use for Small Power Production Facilities

50. Section 292.204(b) of the Commission's regulations⁴⁶ allows small power production facilities to use oil, natural gas or coal in amounts up to and including 25 percent of the total energy input to the facility as calculated during the 12-month period beginning with the date the facility first produces electric energy and any calendar year

⁴³ 31,203 (2006), *order on reh'g*, Order No. 671-A, 71 FR 30585 (May 22, 2006), FERC Stats. & Regs. ¶ 31,219 (2006).

⁴⁴ As defined in section 3(22) of the Federal Power Act, 16 U.S.C. 796(22).

⁴⁵ As defined in section 1262(8) of the Public Utility Holding Company Act of 2005, 42 U.S.C. 16451(8).

⁴⁶ The 10 percent ownership threshold is proposed to be consistent with the 10 percent ownership thresholds used in the definition of a "holding company" in section 1262(8) of the Public Utility Holding Company Act of 2005, 42 U.S.C. 16451(8), and in the definition of "affiliate" in 18 CFR 35.36(a)(9). However, we seek comments on whether a different threshold would be more appropriate in this context.

⁴⁷ 18 CFR 292.204(b).

subsequent to the year in which the facility first produces electric energy. Such use of oil, natural gas or coal is limited to certain purposes specified in section 3(17)(B) of the Federal Power Act as implemented in § 292.204(b)(2) of the Commission's regulations.⁴⁷

51. Item 7 of the current Form No. 556 requires applicants to describe "how fossil fuel use will not exceed 25 percent of the total annual energy input limit," and "how the use of fossil fuel will be limited to the following purposes to conform to Federal Power Act Section 3(17)(B): Ignition, start-up, flame stabilization, control use, and minimal amounts of fuel required to alleviate or prevent unanticipated equipment outages and emergencies directly affecting the public." Experience with this item has indicated two problems. First, because applicants have significant latitude in how they respond, they often make statements which do not, on their face, commit themselves to fuel use that would meet the Commission's requirements for qualifying small power production facilities. While these responses are unlikely to represent an intentional attempt on the part of applicants to circumvent the Commission's regulations for fuel use,⁴⁸ the statements could make enforcement of the Commission's regulations more difficult.

52. On the other hand, applicants who are very specific in their response to item 7 may feel that they have committed themselves to only engage in the particular uses they specified in their Forms 556, despite the fact that the Commission's regulations may permit more flexibility in the use of fossil fuel.

53. We propose a simpler method of certifying compliance with the Commission's fuel use requirements for small power production facilities that should avoid these problems. Rather than requiring applicants to describe how they will comply, we propose to simply state what the fuel use requirements are, and to require the applicant to certify, by checking a box next to each requirement, that they will comply. This proposal will, we believe, obligate the applicant to comply with the stated requirements, while not creating an impression that the applicant must limit its fuel use to some standard which is more stringent than

⁴⁷ 18 CFR 292.204(b)(2).

⁴⁸ Particularly since the wording of the current item 7 of the Form No. 556 states the fuel use requirements of the Commission's regulations, we would find unconvincing any argument that an applicant was justified in violating the fuel use requirements of the Commission's regulations by virtue of its statements in item 7.

that established in the Commission's regulations.

F. Mass and Heat Balance Diagrams for Cogeneration Facilities

54. Item 10 of the current Form No. 556 requires applicants for qualifying cogeneration facility status to provide a mass and heat balance diagram depicting average annual hourly operating conditions. As part of item 10, applicants are required to provide the following on their mass and heat balance diagrams: All fuel flow inputs in Btu/hr. specified using lower heating value, separately indicating fuel inputs for supplementary firing; average net electric output in kW or MW; average net mechanical output in horsepower; number of hours of operation used to determine the average annual hourly facility inputs and outputs; and working fluid flow conditions at input and output of prime mover(s) and at delivery to and return from each useful thermal application. Working fluid flow conditions required to be provided include the following: Flow rates in lbs./hr.; temperature in °F; pressure in psia; and enthalpy in Btu/lb.

55. Some applicants have complained that, for relatively simple cogeneration facilities, some of the information required is meaningless or not known. For example, small diesel generators utilizing jacket water cooling systems to capture waste heat are often certified as qualifying cogeneration facilities. Such systems typically have no steam at any point in the system, and instead use pressurized water or an antifreeze solution to recover the waste heat and transport it to the useful thermal application. For such systems, applicants have complained that specifying pressure has no significance, since the effect of pressure on enthalpy (a measure of thermal energy content) is negligible for liquids at standard conditions. Likewise, applicants have complained that, since pressure in all-liquid systems is not an important design variable, it is often not known to any degree of accuracy in such systems.

56. Some applicants have also pointed out that, in systems which are all liquid water, the extra work required to determine and specify enthalpy is not necessary. Since enthalpy in liquid water is a nearly linear function of temperature (because the specific heat of water does not vary significantly under standard conditions), specification of temperature at each required location and a specification of the specific heat of the working fluid (usually water) is all that is necessary to describe the energy balance of the cogeneration facility.

57. We agree. We propose to include language in new line 10b of the Form No. 556 indicating that, for systems where the working fluid is liquid only (no vapor at any point in the cycle) and where the type of liquid and specific heat of that liquid is clearly indicated on the diagram or in the Miscellaneous section of the Form No. 556, only mass flow rate and temperature (not pressure and enthalpy) need be specified.

58. Our experience has shown that a relatively high level of deficiency and rejection letters for QF applications are a result of noncompliance with the requirements for the mass and heat balance diagram. This is likely due to a combination of the fact the requirements for the mass and heat balance diagram are long, technical and not always clear, and the fact that some applicants do not put sufficient effort and attention into ensuring compliance. To improve reporting and to decrease future noncompliance, we propose to require applicants for qualifying cogeneration facility status to certify compliance with each of the requirements for the mass and heat balance diagram by checking a box next to each written requirement. We expect that, by requiring applicants to proceed box by box through the individual requirements, which will be stated more clearly than in the current Form No. 556, reporting will improve and noncompliance will drop dramatically.

G. EPAct 2005 Cogeneration Facilities

59. In response to EPAct 2005, the Commission implemented in Order No. 671 additional requirements for new cogeneration facilities selling power pursuant to section 210 of PURPA.⁴⁹ The Commission implemented the "productive and beneficial" and "fundamental use" requirements of EPAct 2005 through the inclusion of a new section in the Form No. 556 that required applicants to respond to the text of the statute, providing applicants space to demonstrate compliance with EPAct 2005's requirements. In practice, Form No. 556 has not provided sufficient guidance to applicants through the determination of whether EPAct 2005 applies to their facilities, whether their facilities enjoy a presumption of compliance under

⁴⁹ Congress in EPAct 2005, and the Commission in implementing EPAct 2005, referred to the facilities subject to the EPAct 2005 requirements as "new" cogeneration facilities. 16 U.S.C. 824a-3(n); 18 CFR 292.205(d). To avoid confusion that this "new" label will create as time passes and such facilities are not "new" anymore (except with respect to the date of the implementation of EPAct 2005), we will refer in the proposed Form No. 556 to such facilities as "EPAct 2005 cogeneration facilities."

§ 292.205(d)(4) of the Commission's regulations, or whether such facilities fall within the safe harbor established by the "fundamental use test" in § 292.205(d)(3).

60. We note that, in implementing the "productive and beneficial" requirement of EPAct 2005, the Commission essentially maintained its long-standing "usefulness" standard, except that what it deemed as presumptively useful was now rebuttable.⁵⁰ The current Form No. 556 requirement that applicants demonstrate compliance both with the "productive and beneficial" standard (in item 15) and the "useful" standard (in items 12, 13 and/or 14) can be condensed and streamlined without degrading the information provided or the level of Commission and public oversight of the QF program. We propose to consolidate these requirements into the portion of the proposed Form No. 556 where applicants demonstrate the "usefulness" of the thermal output (lines 12a, 12b, 14a, and 14b of the proposed form).

61. The "fundamental use" requirement for EPAct 2005 cogeneration facilities, on the other hand, does involve data collection that is specific to EPAct 2005 facilities. As such, we propose to implement a new section of the Form No. 556 entitled "EPAct 2005 Requirements for Fundamental Use of Energy Output from Cogeneration Facilities." This section would replace the current "For New Cogeneration Facilities" section. We propose this new section to facilitate an applicant's determination (1) whether the EPAct 2005 cogeneration requirements apply to its facility, given the date on which the facility was originally a QF or originally filed for QF certification; (2) whether its pre-EPAct 2005 facility (if applicable) is subject to EPAct 2005 by virtue of changes to the facility which essentially make it a "new" EPAct 2005 facility; (3) whether its facility is excluded from the "fundamental use" requirement by virtue of the fact that power will not be sold from the facility pursuant to section 210 of PURPA; (4) whether its facility enjoys a rebuttable presumption of compliance with the "fundamental use" requirement by virtue of its small electric output; and/or (5) whether its facility complies with the fundamental use requirement by virtue of meeting the fundamental use test established in § 292.205(d)(3) of the Commission's regulations. If an applicant's facility is found to be subject to the EPAct 2005 requirements, but to fail the

⁵⁰ Order No. 671, FERC Stats. & Regs. ¶ 31.203 at P 17 (2006).

fundamental use test, then the applicant is instructed by line 11d of the proposed Form No. 556 to provide a narrative explanation of and support for why its facility meets the requirement that the electrical, thermal, chemical and mechanical output of an EPAAct 2005 cogeneration facility is used fundamentally for industrial, commercial, residential or institutional purposes and is not intended fundamentally for sale to an electric utility, taking into account technological, efficiency, economic, and variable thermal energy requirements, as well as state laws applicable to sales of electric energy from a QF to its host facility.

62. We seek comments on the proposed "EPAAct 2005 Requirements for Fundamental Use of Energy Output from Cogeneration Facilities" section. In particular, we seek comments on proposed line 11c. In the proposed line 11c, we seek information to be used in determining whether a modification to a pre-EPAAct 2005 cogeneration facility might be so significant that the facility should be considered a new facility that would be subject to the additional requirements (if applicable) for EPAAct 2005 cogeneration facilities. In Order No. 671, the Commission established a rebuttable presumption that a pre-EPAAct 2005 cogeneration facility does not become an EPAAct 2005 cogeneration facility merely because it files for recertification; however, the Commission cautioned that "changes to

an existing cogeneration facility could be so great (such as an increase in capacity from 50 MW to 350 MW) that what an applicant is claiming to be an existing facility should, in fact, be considered a 'new' cogeneration facility at the same site."⁵¹ We will continue this rebuttable presumption, but also require that an applicant filing a self-recertification or an application for Commission recertification for a pre-EPAAct 2005 cogeneration facility provide sufficient information about any changes to the facility to evaluate whether in fact the changes are so significant that the facility should be considered an EPAAct 2005 cogeneration facility.

63. Thus an applicant for recertification of a pre-EPAAct 2005 cogeneration facility which intends to rely upon the rebuttable presumption that recertification of its existing facility does not make the facility subject to the EPAAct 2005 requirements must provide a description of the relevant changes to the facility, including the purpose of the changes, and an explanation why the facility should not be considered an EPAAct 2005 cogeneration facility.

64. We stress that we are not proposing a finding that every facility that has undergone a change should be considered an EPAAct 2005 cogeneration facility; rather, we are proposing to require that an applicant filing a self-recertification or an application for Commission recertification for a pre-EPAAct 2005 cogeneration facility

provide enough information about any changes to the facility to allow the Commission and the public to evaluate the changes.

V. Information Collection Statement

65. The collections of information contained in this proposed rule have been submitted to the Office of Management and Budget for review under section 3507(d) of the Paperwork Reduction Act of 1995.⁵² The Commission solicits comments on the Commission's need for this information, whether the information will have practical utility, the accuracy of the burden estimates, ways to enhance the quality, utility and clarity of the information to be collected or retained, and any suggested methods for minimizing respondents' burden, including the use of automated information techniques.

A. Estimated Annual Burden

66. The Commission has previously broken down its estimated annual burden for completing the Form No. 556 by filing type (self-certification or Commission certification). We believe that breaking down the filings by facility type (small power production facility or cogeneration facility) in addition to filing type will result in a significantly improved burden estimate. Using this method, the total estimated annual time for the collection of information associated with the Form No. 556 is 2,156 hours, calculated as follows:

Facility type	Filing type	Number of respondents	Hours per respondent	Total annual hours
cogeneration facility > 1 MW	self-certification	100	8	800
cogeneration facility > 1 MW	application for Commission certification	3	50	150
small power production facility > 1 MW	self-certification	400	3	1200
small power production facility > 1 MW	application for Commission certification	1	6	6

67. *Information Collection Costs:* The Commission seeks comments on the costs to comply with these requirements. As almost all of the regulation changes are intended to make seeking certification easier, and because we are proposing to exempt applicants for facilities not greater than 1 MW from the certification requirement, the Commission estimates that the collection costs associated with the new form will be less burdensome than with the existing form. Although the length of the form has increased, this is a result of the proposal to change the form to more effectively "walk" applicants through the certification and compliance determinations that they

currently have to research and process on their own.

Title: FERC Form No. 556, "Certification of qualifying facility (QF) status for small power production or cogeneration facility."

Action: Proposed information collection.

OMB Control No.: 1902-0075.

Respondents: Residences, businesses or other for profit entities, and government agencies.

Frequency of responses: On occasion.

Necessity of the information: The Form No. 556 was established in Order No. 575 to allow an applicant to self-certify or to request the Commission to determine whether a facility meets the

criteria for qualifying small power production or cogeneration status under the Commission's regulations, and thus whether the applicant is eligible to receive the benefits available to it under PURPA.

Internal review: The Commission has reviewed its proposed changes to the requirements pertaining to the certification of qualifying small power production and cogeneration facilities and determined the proposed changes appear to decrease the existing burden on applicants. These proposed requirements conform to the Commission's plan for efficient information collection, communication and management within the energy

⁵¹ *Id.* P 115.

⁵² 44 U.S.C. 3507(d).

industry. The Commission has assured itself, by means of internal review, that there is specific, objective support for the burden estimates associated with the information requirements.

68. Interested persons may obtain information on the reporting requirements by contacting: Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426 [Attention: Michael Miller, Office of the Deputy Chief Information Officer, phone: (202) 502-8415, fax: (202) 273-0873, e-mail: Michael.Miller@ferc.gov]. Comments concerning the collection of information and the associated burden estimates, should be sent to the contact listed above and to the Office of Management and Budget, Office of Information and Regulatory Affairs, Washington, DC 20503 [Attention: Desk Officer for the Federal Energy Regulatory Commission, phone (202) 395-4638; fax (202) 395-7285].

VI. Environmental Analysis

69. The Commission is required to prepare an Environmental Assessment or an Environmental Impact Statement for any action that may have a significant adverse effect on the human environment.⁵³ No environmental consideration is needed for the promulgation of a rule that addresses information gathering, analysis, and dissemination.⁵⁴ These proposed rules, if finalized, involve information gathering, analysis, and dissemination. Consequently, neither an Environmental Impact Statement nor Environmental Assessment is required.

VII. Regulatory Flexibility Act

70. The Regulatory Flexibility Act of 1980 (RFA)⁵⁵ requires rulemakings to contain either a description or analysis of the effect that the rule will have on small entities or a certification that the rule will not have a significant economic impact on a substantial number of small entities. In this notice, we propose three different types of regulatory changes, and we address each in turn.

71. First, we propose to clarify and streamline the Form No. 556. These changes make the form easier for applicants, whether large or small, to complete, because the proposed form leads applicants step-by-step through the compliance determinations.

72. Second, we propose certain limited additional disclosures of information. In particular, we propose

(1) to collect in line 3g of the proposed form the geographic coordinates of facilities that do not have a street address, and (2) to collect certain information used to determine applicability of the EPC Act 2005 cogeneration requirements that was not previously explicitly required to be included in Form No. 556.

73. The requirement to report geographic coordinates is applicable only to those facilities that do not have a street address and is therefore not generally applicable to all applicants. Moreover, in most cases, geographic coordinates can be obtained from a simple web search (with help provided by the instructions and the Commission's website); a GPS device (including some cellular phones); the use of free computer programs (such as Google Earth); or the review of certain documents, such as a property survey, various engineering or construction drawings, a property deed, or a municipal or county map showing property lines.

74. The new information proposed to be collected from applicants for cogeneration facilities in lines 11a through 11f serves to guide the applicants through the determination whether the EPC Act 2005 cogeneration requirements apply to their facilities. The process of completing lines 11a through 11f replicates, but in a clearer and more concise manner, the process that such applicants already have to go through in completing the current form. Completing lines 11a through 11f should substantially decrease the burden of complying with the EPC Act 2005 cogeneration requirements for most or all applicants for cogeneration facilities. In the absence of this step-by-step guide proposed in lines 11a through 11f, applicants (particularly small applicants) must independently research the requirements and determine compliance with the relatively complex EPC Act 2005 cogeneration requirements.

75. Third, we propose to require applicants for certification of QF status to submit their Forms 556 electronically, via the Commission's eFiling website. We also propose, however, to exempt applicants for facilities with net power production capacities of 1 MW and smaller from any filing requirement. If both of these proposals are adopted, then the electronic filing requirement would not apply to applicants for small QFs. We believe that any applicant for a facility larger than 1 MW should have access to the resources needed to make an electronic filing.

VIII. Comment Procedures

76. The Commission invites interested persons to submit comments on the matters and issues proposed in this notice to be adopted, including any related matters or alternative proposals that commenters may wish to discuss. Comments are due on or before December 21, 2009. Comments must refer to Docket No. RM09-23-000, and must include the commenter's name, the organization he or she represents, if applicable, and his or her address.

77. The Commission encourages comments to be filed electronically via the eFiling link on the Commission's web site at <http://www.ferc.gov>. The Commission accepts most standard word processing formats, and commenters may attach additional files with supporting information in certain other file formats. Commenters filing electronically do not need to make a paper filing.

78. Commenters who are not able to file comments electronically must send an original and 14 copies of their comments to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street, NE., Washington, DC 20426.

79. All comments will be placed in the Commission's public files and may be viewed, printed, or downloaded remotely as described in the Document Availability section below. Commenters on this notice of proposed rulemaking are not required to serve copies of their comments on other commenters.

IX. Document Availability

80. In addition to publishing the full text of this document (with the exception of the Form No. 556 itself—which will be available in eLibrary and posted at <http://www.ferc.gov/QF>) in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the Internet through the Commission's home page (<http://www.ferc.gov>) and in the Commission's Public Reference Room during normal business hours (8:30 a.m. to 5 p.m. Eastern time) at 888 First Street, NE., Room 2A, Washington, DC 20426.

81. From the Commission's home page on the Internet, this information is available in the Commission's document management system, eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

⁵³ See *Regulations Implementing the National Environmental Policy Act of 1969*, Order No. 486, FERC Stats. & Regs. ¶ 30,783 (1987).

⁵⁴ See 18 CFR 380.4(a)(5).

⁵⁵ 5 U.S.C. 601-12.

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

List of Subjects

18 CFR Part 131

Electric power, Natural gas, Reporting and recordkeeping requirements.

18 CFR Part 292

Electric power, Electric power plants, Electric utilities.

By direction of the Commission.

Nathaniel J. Davis, Sr.,
Deputy Secretary.

In consideration of the foregoing, the Commission proposes to amend parts 131 and 292 of Title 18 of the *Code of Federal Regulations*, as set forth below:

Subchapter D—Approved Forms, Federal Power Act and Public Utility Regulatory Policies Act of 1978

PART 131—FORMS

1. The authority citation for part 131 continues to read as follows:

Authority: 16 U.S.C. 791a–825r, 2601–2645; 31 U.S.C. 9701; 42 U.S.C. 7101–7352.

2. Section 131.80 is revised to read as follows:

§ 131.80 FERC Form No. 556, Certification of qualifying facility (QF) status for a small power production or cogeneration facility.

(a) *Who must file.* Any person seeking to certify a facility as a qualifying facility pursuant to sections 3(17) or 3(18) of the Federal Power Act, 16 U.S.C. 796(3)(17), (3)(18), unless otherwise exempted or granted a waiver by Commission rule or order pursuant to § 292.203(d), must complete and file the Form of Certification of Qualifying Facility (QF) Status for a Small Power Production or Cogeneration Facility, FERC Form No. 556. Every Form of Certification of Qualifying Status must be submitted on the FERC Form No. 556 then in effect and must be prepared in accordance with the instructions incorporated in that form.

(b) *Availability of FERC Form No. 556.* The currently effective FERC Form No. 556 shall be made available for download from the Commission's Web site.

(c) *How to file a FERC Form No. 556.* All applicants must file their FERC Forms No. 556 electronically via the Commission's eFiling Web site.

Subchapter K—Regulations Under the Public Utility Regulatory Policies Act of 1978

PART 292—REGULATIONS UNDER SECTIONS 201 AND 210 OF THE PUBLIC UTILITY REGULATORY POLICIES ACT OF 1978 WITH REGARD TO SMALL POWER PRODUCTION AND COGENERATION

1. The authority citation for part 292 continues to read as follows:

Authority: 16 U.S.C. 791a–825r, 2601–2645; 31 U.S.C. 9701; 42 U.S.C. 7101–7352.

2. Revise § 292.203 to read as follows:

§ 292.203 General requirements for qualification.

(a) *Small power production facilities.* Except as provided in paragraph (c) of this section, a small power production facility is a qualifying facility if it:

(1) Meets the maximum size criteria specified in § 292.204(a);

(2) Meets the fuel use criteria specified in § 292.204(b); and

(3) Unless exempted by paragraph (d), has filed with the Commission a notice of self-certification, pursuant to § 292.207(a); or has filed with the Commission an application for Commission certification, pursuant to § 292.207(b)(1), that has been granted.

(b) *Cogeneration facilities.* A cogeneration facility, including any diesel and dual-fuel cogeneration facility, is a qualifying facility if it:

(1) Meets any applicable standards and criteria specified in §§ 292.205(a), (b) and (d); and

(2) Unless exempted by paragraph (d), has filed with the Commission a notice of self-certification, pursuant to § 292.207(a); or has filed with the Commission an application for Commission certification, pursuant to § 292.207(b)(1), that has been granted.

(c) *Hydroelectric small power production facilities located at a new dam or diversion.* (1) A hydroelectric small power production facility that impounds or diverts the water of a natural watercourse by means of a new dam or diversion (as that term is defined in § 292.202(p)) is a qualifying facility if it meets the requirements of:

(i) Paragraph (a) of this section; and

(ii) Section 292.208.

(2) [Reserved]

(d) *Exemptions and waivers from filing requirement.* (1) Any facility with a net power production capacity of 1 MW or less is exempt from the filing requirements of paragraphs (a)(3) and (b)(2) of this section.

(2) The Commission may waive the requirement of paragraphs (a)(3) and (b)(2) of this section for good cause. Any

applicant seeking waiver of paragraphs (a)(3) and (b)(2) of this section must file a petition for declaratory order describing in detail the reasons waiver is being sought.

3. In § 292.204, paragraph (a)(1) is revised and paragraph (a)(4) is added to read as follows:

§ 292.204 Criteria for qualifying small power production facilities.

(a) *Size of the facility*—(1) *Maximum size.* Except as provided in paragraph (a)(4) of this section, the power production capacity of a facility for which qualification is sought, together with the power production capacity of any other small power production facilities that use the same energy resource, are owned by the same person(s) or its affiliates, and are located at the same site, may not exceed 80 megawatts.

* * * * *

(4) *Exception.* Facilities meeting the criteria in section 3(17)(E) of the Federal Power Act (16 U.S.C. 796(17)(E)) have no maximum size, and the power production capacity of such facilities shall be excluded from consideration when determining the maximum size of other small power production facilities within one mile of such facilities.

* * * * *

4. In § 292.205, paragraph (d) introductory text is revised to read as follows:

§ 292.205 Criteria for qualifying cogeneration facilities.

* * * * *

(d) *Criteria for new cogeneration facilities.* Notwithstanding paragraphs (a) and (b) of this section, any cogeneration facility that was either not a qualifying cogeneration facility on or before August 8, 2005, or that had not filed a notice of self-certification or an application for Commission certification as a qualifying cogeneration facility under § 292.207 of this chapter prior to February 2, 2006, and which is seeking to sell electric energy pursuant to section 210 of the Public Utility Regulatory Policies Act of 1978, 16 U.S.C. 824a–1, must also show:

* * * * *

5. In § 292.207, paragraphs (a) through (d)(1)(i) are revised to read as follows:

§ 292.207 Procedures for obtaining qualifying status.

(a) *Self-certification.* The qualifying facility status of an existing or a proposed facility that meets the requirements of § 292.203 may be self-certified by the owner or operator of the facility or its representative by properly completing a Form No. 556 and filing

that form with the Commission, pursuant to § 131.80 of this chapter, and complying with paragraph (c) of this section.

(b) *Optional procedure*—(1) *Application for Commission certification.* In lieu of the self-certification procedures in paragraph (a) of this section, an owner or operator of an existing or a proposed facility, or its representative, may file with the Commission an application for Commission certification that the facility is a qualifying facility. The application must be accompanied by the fee prescribed by part 381 of this chapter, and the applicant for Commission certification must comply with paragraph (c) of this section.

(2) *General contents of application.* The application must include a properly completed Form No. 556 pursuant to § 131.80 of this chapter.

(3) *Commission action.* (i) Within 90 days of the later of the filing of an application or the filing of a supplement, amendment or other change to the application, the Commission will either: inform the applicant that the application is deficient; or issue an order granting or denying the application; or toll the time for issuance of an order. Any order denying certification shall identify the specific requirements which were not met. If the Commission does not act within 90 days of the date of the latest filing, the application shall be deemed to have been granted.

(ii) For purposes of paragraph (b) of this section, the date an application is filed is the date by which the Secretary of the Commission has received all of the information and the appropriate filing fee necessary to comply with the requirements of this Part.

(c) *Notice requirements*—(1) *General.* An applicant filing a self-certification, self-recertification, application for Commission certification or application for Commission recertification of the qualifying status of its facility must concurrently serve a copy of such filing on each electric utility with which it expects to interconnect, transmit or sell electric energy to, or purchase supplementary, standby, back-up or maintenance power from, and the State regulatory authority of each state where the facility and each affected electric utility is located. The Commission will publish a notice in the **Federal Register** for each application for Commission certification and for each self-certification of a cogeneration facility that is subject to the requirements of § 292.205(d).

(2) *Facilities of 500 kW or more.* An electric utility is not required to purchase electric energy from a facility with a net power production capacity of 500 kW or more until 90 days after the facility meets the notice requirements in paragraph (c)(1) of this section.

(d) *Revocation of qualifying status.* (1)(i) If a qualifying facility fails to conform with any material facts or representations presented by the cogenerator or small power producer in its submittals to the Commission, the notice of self-certification or Commission order certifying the qualifying status of the facility may no longer be relied upon. At that point, if the facility continues to conform to the Commission's qualifying criteria under this part, the cogenerator or small power producer may file either a notice of self-recertification of qualifying status pursuant to the requirements of paragraph (a) of this section, or an

application for Commission recertification pursuant to the requirements of paragraph (b) of this section, as appropriate.

* * * * *

6. In § 292.601, paragraph (a) is revised to read as follows:

§ 292.601 Exemption to qualifying facilities from the Federal Power Act.

(a) *Applicability.* This section applies to qualifying facilities, other than those described in paragraph (b) of this section. This section also applies to qualifying facilities that meet the criteria of section 3(17)(E) of the Federal Power Act (16 U.S.C. 796(17)(E)), notwithstanding paragraph (b) of this section.

* * * * *

7. In § 292.602, revise the section heading and paragraph (c)(1) to read as follows:

§ 292.602 Exemption to qualifying facilities from the Public Utility Holding Company Act of 2005 and certain State laws and regulations.

* * * * *

(c) *Exemption from certain State laws and regulations.* (1) Any qualifying facility described in paragraph (a) of this section shall be exempted (except as provided in paragraph (c)(2) of this section) from State laws or regulations respecting:

* * * * *

Note: The following Appendix will not be published in the *Code of Federal Regulations*.

Appendix A—Proposed FERC Form No. 556

BILLING CODE 6717-01-P

FEDERAL ENERGY REGULATORY COMMISSION
WASHINGTON, DC**Form 556** Certification of Qualifying Facility (QF) Status for a Small Power
Production or Cogeneration Facility**General**

Information about the Commission's QF program, answers to frequently asked questions about QF requirements or completing this form, and contact information for QF program staff are available at the Commission's QF website, www.ferc.gov/QF. The Commission's QF website also provides links to the Commission's QF regulations (18 C.F.R. § 131.80 and Part 292), as well as other statutes and orders pertaining to the Commission's QF program.

Who Must File

Any applicant seeking QF status or recertification of QF status for a generating facility with a net power production capacity (as determined in lines 7a through 7g below) greater than 1000 kW must file a self-certification or an application for Commission certification of QF status, which includes a properly completed Form 556. Any applicant seeking QF status for a generating facility with a net power production capacity 1000 kW or less is exempt from the certification requirement, and is therefore not required to complete or file a Form 556. See 18 C.F.R. § 292.203.

How to Complete the Form 556

This form will be easiest to understand and complete if you respond to the lines in the order they are presented, following the instructions given. Certain lines in this form will be automatically calculated based on responses to previous lines, with the relevant formulas shown. You must respond to all of the previous lines within a section before the results of an automatically calculated field will be displayed. If you disagree with the results of any automatic calculation on this form, contact Commission staff to discuss the discrepancy before filing.

You must complete all lines in this form unless instructed otherwise. Do not alter this form or save this form in a different format. Incomplete or altered forms, or forms saved in formats other than PDF, will be rejected.

How to File a Completed Form 556

Applicants are required to file their Form 556 electronically through the Commission's eFiling website (see instructions on page 2). By filing electronically, you will reduce your filing burden, save paper resources, save postage or courier charges, help keep Commission expenses to a minimum, and receive a much faster confirmation (via an email containing the docket number assigned to your facility) that the Commission has received your filing.

If you are simultaneously filing both a waiver request and a Form 556 as part of an application for Commission certification, see the "Waiver Requests" section on page 3 for more information on how to file.

Paperwork Reduction Act Notice

This form is approved by the Office of Management and Budget (OMB Control No. [number], expiration [date]). Compliance with the information requirements established by the FERC Form No. 556 is required to obtain or maintain status as a QF. See 18 C.F.R. § 131.80 and Part 292. 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 estimated burden for completing the FERC Form No. 556, including gathering and reporting information, is as follows: 3 hours for self-certification of a small power production facility, 8 hours for self-certifications of a cogeneration facility, 6 hours for an application for Commission certification of a small power production facility, and 50 hours for an application for Commission certification of a cogeneration facility. Send comments regarding this burden estimate or any aspect of this collection of information, including suggestions for reducing this burden, to the following: Michael Miller, Office of the Executive Director (ED-34), Federal Energy Regulatory Commission, 888 First Street N.E., Washington, DC 20426; and Desk Officer for FERC, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503 (oir_submission@omb.eop.gov). Include the Control No. [number] in any correspondence.

Electronic Filing (eFiling)

To electronically file your Form 556, visit the Commission's QF website at www.ferc.gov/QF and click the eFiling link.

If you are eFiling your first document, you will need to register with your name, email address, mailing address, and phone number. If you are registering on behalf of an employer, then you will also need to provide the employer name, alternate contact name, alternate contact phone number and alternate contact email.

Once you are registered, log in to eFiling with your registered email address and the password that you created at registration. Follow the instructions. When prompted, select one of the following QF-related filing types, as appropriate, from the Electric or General filing category.

Filing category	Filing Type as listed in eFiling	Description
Electric	(Fee) Application for Commission Cert. as Cogeneration QF	Use to submit an application for Commission certification or Commission recertification of a cogeneration facility as a QF.
	(Fee) Application for Commission Cert. as Small Power QF	Use to submit an application for Commission certification or Commission recertification of a small power production facility as a QF.
	Self-Certification Notice (QF, EG, FC)	Use to submit a notice of self-certification of your facility (cogeneration or small power production) as a QF.
	Self-Recertification of Qualifying Facility (QF)	Use to submit a notice of self-recertification of your facility (cogeneration or small power production) as a QF.
	Supplemental Information or Request	Use to correct or supplement a Form 556 that was submitted with errors or omissions, or for which Commission staff has requested additional information. Do <u>not</u> use this filing type to report new changes to a facility or its ownership; rather, use a self-recertification or Commission recertification to report such changes.
General	(Fee) Petition for Declaratory Order (not under FPA Part 1)	Use to submit a petition for declaratory order granting a waiver of Commission QF regulations pursuant to 18 C.F.R. §§ 292.204(a) (3) and/or 292.205(c). A Form 556 is not required for a petition for declaratory order unless Commission recertification is being requested as part of the petition.

You will be prompted to submit your filing fee, if applicable, during the electronic submission process. Filing fees can be paid via electronic bank account debit or credit card.

During the eFiling process, you will be prompted to select your file(s) for upload from your computer.

Filing Fee

No filing fee is required if you are submitting a self-certification or self-recertification of your facility as a QF pursuant to 18 C.F.R. § 292.207(a).

A filing fee is required if you are filing either of the following:

- (1) an application for Commission certification or recertification of your facility as a QF pursuant to 18 C.F.R. § 292.207(b), or
- (2) a petition for declaratory order granting waiver pursuant to 18 C.F.R. §§ 292.204(a)(3) and/or 292.205(c).

The current fees for applications for Commission certifications and petitions for declaratory order can be found by visiting the Commission's QF website at www.ferc.gov/QF and clicking the Fee Schedule link.

You will be prompted to submit your filing fee, if applicable, during the electronic filing process described on page 2.

Required Notice to Utilities and State Regulatory Authorities

Pursuant to 18 C.F.R. § 292.207(a)(ii), you must provide a copy of your self-certification or request for Commission certification to the utilities with which the facility will interconnect and/or transact, as well as to the State regulatory authorities of the states in which your facility and those utilities reside. Links to information about the regulatory authorities in various states can be found by visiting the Commission's QF website at www.ferc.gov/QF and clicking the Notice Requirements link.

What to Expect From the Commission After You File

An applicant filing a Form 556 electronically will receive an email message acknowledging receipt of the filing and showing the docket number assigned to the filing. Such email is typically sent within one business day, but may be delayed pending confirmation by the Secretary of the Commission of the contents of the filing.

An applicant submitting a self-certification of QF status should expect to receive no documents from the Commission, other than the electronic acknowledgement of receipt described above. Consistent with its name, a self-certification is a certification by the applicant itself that the facility meets the relevant requirements for QF status, and does not involve a determination by the Commission as to the status of the facility. An acknowledgement of receipt of a self-certification, in particular, does not represent a determination by the Commission with regard to the QF status of the facility. An applicant self-certifying may, however, receive a rejection, revocation or deficiency letter if its application is found, during periodic compliance reviews, not to comply with the relevant requirements.

An applicant submitting a request for Commission certification will receive an order either granting or denying certification of QF status, or a letter requesting additional information or rejecting the application. Pursuant to 18 C.F.R. § 292.207(b)(3), the Commission must act on an application for Commission certification within 90 days of the later of the filing date of the application or the filing date of a supplement, amendment or other change to the application.

Waiver Requests

18 C.F.R. § 292.204(a)(3) allows an applicant to request a waiver to modify the method of calculation pursuant to 18 C.F.R. § 292.204(a)(2) to determine if two facilities are considered to be located at the same site, for good cause. 18 C.F.R. § 292.205(c) allows an applicant to request waiver of the requirements of 18 C.F.R. §§ 292.205(a) and (b) for operating and efficiency upon a showing that the facility will produce significant energy savings. A request for waiver of these requirements must be submitted as a petition for declaratory order, with the appropriate filing fee for a petition for declaratory order. Applicants requesting Commission recertification as part of a request for waiver of one of these requirements should electronically submit their completed Form 556 along with their petition for declaratory order, rather than filing their Form 556 as a separate request for Commission recertification. Only the filing fee for the petition for declaratory order must be paid to cover both the waiver request and the request for recertification if such requests are made simultaneously.

18 C.F.R. § 292.203(d)(2) allows an applicant to request a waiver of the Form 556 filing requirements, for good cause. Applicants filing a petition for declaratory order requesting a waiver under 18 C.F.R. § 292.203(d)(2) do not need to complete or submit a Form 556 with their petition.

Geographic Coordinates

If a street address does not exist for your facility, then line 3c of the Form 556 requires you to report your facility's geographic coordinates (latitude and longitude). Geographic coordinates may be obtained from several different sources. You can find links to online services that show latitude and longitude coordinates on online maps by visiting the Commission's QF webpage at www.ferc.gov/QF and clicking the Geographic Coordinates link. You may also be able to obtain your geographic coordinates from a GPS device, Google Earth (available free at <http://earth.google.com>), a property survey, various engineering or construction drawings, a property deed, or a municipal or county map showing property lines.

Filing Privileged Data or Critical Energy Infrastructure Information in a Form 556

The Commission's regulations provide procedures for applicants to either (1) request that any information submitted with a Form 556 be given privileged treatment because the information is exempt from the mandatory public disclosure requirements of the Freedom of Information Act, 5 U.S.C. § 552, and should be withheld from public disclosure; or (2) identify any documents containing critical energy infrastructure information (CEII) as defined in 18 C.F.R. § 388.113 that should not be made public. If you are seeking privileged treatment or CEII status for any data in your Form 556, indicate as such below:

- Applicant requests privileged treatment of data contained in the following line numbers; this data has been redacted from the public version of this form (see instructions below):

- Applicant is identifying CEII information contained in the following line numbers; this data has been redacted from the public version of this form (see instructions below):

If you are seeking privileged treatment or CEII status for any data in your Form 556, then you must follow the procedures in 18 C.F.R. § 388.112. See www.ferc.gov/help/filing-guide/file-ceii.asp for more information.

Among other things (see 18 C.F.R. § 388.112 for other requirements), applicants seeking privileged treatment or CEII status for data submitted in a Form 556 must file both (1) a complete version of the Form 556 (containing the privileged and/or CEII data), and (2) a public version of the Form 556 (with the privileged and/or CEII data redacted). The eFiling process described on page 2 will allow you to identify which documents you submit are public, privileged and/or CEII. The filenames for such documents should begin with "Public", "Priv", or "CEII", as applicable, to clearly indicate the security status of the file. Both versions of the Form 556 should be unaltered PDF copies of the Form 556, as available for download from www.ferc.gov/QF. To redact data from the public copy of the submittal, simply delete it from the Form. Be sure to identify above all redacted fields.

The Commission is not responsible for detecting or correcting filer errors, including those errors related to security designation. If your documents contain sensitive information, make sure they are filed using the proper security designation.

FEDERAL ENERGY REGULATORY COMMISSION
WASHINGTON, DC

Form 556 Certification of Qualifying Facility (QF) Status for a Small Power
Production or Cogeneration Facility

Application Information	1a Full name of applicant (legal entity on whose behalf qualifying facility status is sought for this facility)		
	1b Applicant street address		
	1c City		1d State/province
	1e Postal code	1f Country (if not United States)	1g Telephone number
	1h Has the instant facility ever previously been certified as a QF? Yes <input type="checkbox"/> No <input type="checkbox"/>		
	1i If yes, provide the docket number of the last known QF filing pertaining to this facility: QF ____ - ____ - ____		
	1j Under which certification process is the applicant making this filing?		
	<input type="checkbox"/> Notice of self-certification (see note below) <input type="checkbox"/> Application for Commission certification (requires filing fee; see "Filing Fee" section on page 3)		
	Note: a notice of self-certification is a notice by the applicant itself that its facility complies with the requirements for QF status. A notice of self-certification does not establish a proceeding, and the Commission does not review a notice of self-certification to verify compliance. See the "What to Expect From the Commission After You File" section on page 3 for more information.		
	1k What type(s) of QF status is the applicant seeking for its facility? (check all that apply)		
<input type="checkbox"/> Qualifying small power production facility status <input type="checkbox"/> Qualifying cogeneration facility status			
1l What is the purpose and effective date(s) of this filing?			
<input type="checkbox"/> Original certification; facility anticipated to be installed by _____ and to begin operation on _____			
<input type="checkbox"/> Change(s) to a previously certified facility to be effective on _____ (check one category of change below, and describe change in the Miscellaneous section starting on page 19)			
<input type="checkbox"/> Name change and/or other administrative change(s)			
<input type="checkbox"/> Change in ownership			
<input type="checkbox"/> Change(s) affecting plant equipment, fuel use, power production capacity and/or cogeneration thermal output			
1m If any of the following three statements is true, check the box(es) that describe your situation and complete the form to the extent possible, explaining any special circumstances in the Miscellaneous section starting on page 19.			
<input type="checkbox"/> The instant facility complies with the Commission's QF requirements by virtue of a waiver of certain regulations previously granted by the Commission in an order dated _____			
<input type="checkbox"/> The instant facility would comply with the Commission's QF requirements if a petition for waiver submitted concurrently with this application is granted			
<input type="checkbox"/> The instant facility complies with the Commission's regulations, but has special circumstances, such as the employment of unique or innovative technologies not contemplated by the structure of this form, that make the demonstration of compliance via this form difficult or impossible			

FERC Form 556

All Facilities

Contact Information	2a Name of contact person		2b Telephone number	
	2c Which of the following describes the contact person's relationship to the applicant? (check one) <input type="checkbox"/> Applicant (self) <input type="checkbox"/> Employee or partner of applicant authorized to represent the applicant on this matter <input type="checkbox"/> Employee of a company affiliated with the applicant authorized to represent the applicant on this matter <input type="checkbox"/> Lawyer, consultant, or other representative authorized to represent the applicant on this matter			
	2d Company or organization name			
	2e Street address (if same as Applicant, click here and skip to line 3a) <input type="checkbox"/>			
	2f City		2g State/province	
	2h Postal code		2i Country (if not United States)	
	Facility Identification and Location	3a Facility name		
3b Street address (if a street address does not exist for the facility, click here and skip to line 3c) <input type="checkbox"/>				
3c Geographic coordinates: If you indicated in line 3b that no street address exists for your facility, then you must specify the latitude and longitude coordinates of the facility in degrees (to three decimal places). Use the following formula to convert to decimal degrees from degrees, minutes and seconds: decimal degrees = degrees + (minutes/60) + (seconds/3600). See the "Geographic Coordinates" section on page 4 for help. If you provided a street address for your facility in line 3b, then specifying the geographic coordinates below is optional. Longitude <input type="checkbox"/> East (+) _____ degrees Latitude <input type="checkbox"/> North (+) _____ degrees <input type="checkbox"/> West (-) _____ degrees <input type="checkbox"/> South (-) _____ degrees				
3d City (if unincorporated, check here and enter nearest city) <input type="checkbox"/>		3e State/province		
3f County (or check here for independent city) <input type="checkbox"/>		3g Country (if not United States)		
Transacting Utilities	Identify the electric utilities that are contemplated to transact with the facility.			
	4a Identify utility interconnecting with the facility			
	4b Identify utilities providing wheeling service, if any			
	4c Identify utilities purchasing the useful electric power output, if any			
	4d Identify utilities providing supplementary power, backup power, maintenance power, and/or interruptible power service, if any			

FERC Form 556

All Facilities

Ownership and Operation

5a Direct ownership as of effective date: Identify all direct owners of the facility holding at least 10 percent equity interest. For each identified owner, also (1) indicate whether that owner is an electric utility, as defined in section 3(22) of the Federal Power Act (16 U.S.C. 796(22)), or a holding company, as defined in section 1262(8) of the Public Utility Holding Company Act of 2005 (42 U.S.C. 16451(8)), and (2) for owners which are electric utilities or holding companies, provide the percentage of equity interest in the facility held by that owner. If no direct owners hold at least 10 percent equity interest in the facility, then provide the required information for the two direct owners with the largest equity interest in the facility.

	Full legal names of direct owners	Electric utility or holding company	If Yes, % equity interest
1)	_____	Yes <input type="checkbox"/> No <input type="checkbox"/>	_____ %
2)	_____	Yes <input type="checkbox"/> No <input type="checkbox"/>	_____ %
3)	_____	Yes <input type="checkbox"/> No <input type="checkbox"/>	_____ %
4)	_____	Yes <input type="checkbox"/> No <input type="checkbox"/>	_____ %
5)	_____	Yes <input type="checkbox"/> No <input type="checkbox"/>	_____ %
6)	_____	Yes <input type="checkbox"/> No <input type="checkbox"/>	_____ %
7)	_____	Yes <input type="checkbox"/> No <input type="checkbox"/>	_____ %
8)	_____	Yes <input type="checkbox"/> No <input type="checkbox"/>	_____ %
9)	_____	Yes <input type="checkbox"/> No <input type="checkbox"/>	_____ %
10)	_____	Yes <input type="checkbox"/> No <input type="checkbox"/>	_____ %

Check here and continue in the Miscellaneous section starting on page 19 if additional space is needed

5b Upstream (i.e., indirect) ownership as of effective date: Identify all upstream (i.e., indirect) owners of the facility that both (1) hold at least 10 percent equity interest in the facility, and (2) are electric utilities, as defined in section 3(22) of the Federal Power Act (16 U.S.C. 796(22)), or holding companies, as defined in section 1262(8) of the Public Utility Holding Company Act of 2005 (42 U.S.C. 16451(8)). Also provide the percentage of equity interest in the facility held by such owners. Enter "None" at the first line if no such owners exist.

	Full legal names of electric utility or holding company upstream owners	% equity interest
1)	_____	_____ %
2)	_____	_____ %
3)	_____	_____ %
4)	_____	_____ %
5)	_____	_____ %
6)	_____	_____ %
7)	_____	_____ %
8)	_____	_____ %
9)	_____	_____ %
10)	_____	_____ %

Check here and continue in the Miscellaneous section starting on page 19 if additional space is needed

5c Identify the facility operator

Energy Input

6a Describe the primary energy input: (check one main category and, if applicable, one subcategory)

- | | | |
|--|--|---|
| <input type="checkbox"/> Biomass (specify) | <input type="checkbox"/> Renewable resources (specify) | <input type="checkbox"/> Geothermal |
| <input type="checkbox"/> Landfill gas | <input type="checkbox"/> Hydro power - river | <input type="checkbox"/> Fossil fuel (specify) |
| <input type="checkbox"/> Manure digester gas | <input type="checkbox"/> Hydro power - tidal | <input type="checkbox"/> Coal (not waste) |
| <input type="checkbox"/> Municipal solid waste | <input type="checkbox"/> Hydro power - wave | <input type="checkbox"/> Fuel oil/diesel |
| <input type="checkbox"/> Sewage digester gas | <input type="checkbox"/> Solar - photovoltaic | <input type="checkbox"/> Natural gas (not waste) |
| <input type="checkbox"/> Wood | <input type="checkbox"/> Solar - thermal | <input type="checkbox"/> Other fossil fuel
(describe on page 19) |
| <input type="checkbox"/> Other biomass (describe on page 19) | <input type="checkbox"/> Wind | |
| <input type="checkbox"/> Waste (specify type below in line 6b) | <input type="checkbox"/> Other renewable resource
(describe on page 19) | <input type="checkbox"/> Other (describe on page 19) |

6b If you specified "waste" as the primary energy input in line 6a, indicate the type of waste fuel used: (check one)

- Waste fuel listed in 18 C.F.R. § 292.202(b) (specify one of the following)
- Anthracite culm produced prior to July 23, 1985
 - Anthracite refuse that has an average heat content of 6,000 Btu or less per pound and has an average ash content of 45 percent or more
 - Bituminous coal refuse that has an average heat content of 9,500 Btu per pound or less and has an average ash content of 25 percent or more
 - Top or bottom subbituminous coal produced on Federal lands or on Indian lands that has been determined to be waste by the United States Department of the Interior's Bureau of Land Management (BLM) or that is located on non-Federal or non-Indian lands outside of BLM's jurisdiction, provided that the applicant shows that the latter coal is an extension of that determined by BLM to be waste
 - Coal refuse produced on Federal lands or on Indian lands that has been determined to be waste by the BLM or that is located on non-Federal or non-Indian lands outside of BLM's jurisdiction, provided that applicant shows that the latter is an extension of that determined by BLM to be waste
 - Lignite produced in association with the production of montan wax and lignite that becomes exposed as a result of such a mining operation
 - Gaseous fuels (except natural gas and synthetic gas from coal) (describe on page 19)
 - Waste natural gas from gas or oil wells (describe on page 19 how the gas meets the requirements of 18 C.F.R. § 2.400 for waste natural gas; include with your filing any materials necessary to demonstrate compliance with 18 C.F.R. § 2.400)
 - Materials that a government agency has certified for disposal by combustion (describe on page 19)
 - Heat from exothermic reactions (describe on page 19)
 - Residual heat (describe on page 19)
 - Used rubber tires
 - Plastic materials
 - Refinery off-gas
 - Petroleum coke
- Other waste energy input that has little or no commercial value and exists in the absence of the qualifying facility industry (describe in the Miscellaneous section starting on page 19; include a discussion of the fuel's lack of commercial value and existence in the absence of the qualifying facility industry)

6c Provide the average energy input, calculated on a calendar year basis, in terms of Btu/h for the following fossil fuel energy inputs, and provide the related percentage of the total average annual energy input to the facility (18 C.F.R. § 292.202(j)). For any oil or natural gas fuel, use lower heating value (18 C.F.R. § 292.202(m)).

Fuel	Annual average energy input for specified fuel	Percentage of total annual energy input
Natural gas	Btu/h	%
Oil-based fuels	Btu/h	%
Coal	Btu/h	%

FERC Form 556

All Facilities

Technical Facility Information

Indicate the maximum gross and maximum net electric power production capacity of the facility at the point(s) of delivery by completing the worksheet below. Respond to all items. If any of the parasitic loads and/or losses identified in lines 7b through 7e are negligible, enter zero for those lines.

7a The maximum gross power production capacity at the terminals of the individual generator(s) under the most favorable anticipated design conditions	kW
7b Parasitic station power used at the facility to run equipment which is necessary and integral to the power production process (boiler feed pumps, fans/blowers, office or maintenance buildings directly related to the operation of the power generating facility, etc.). If this facility includes non-power production processes (for instance, power consumed by a cogeneration facility's thermal host), do not include any power consumed by the non-power production activities in your reported parasitic station power.	kW
7c Electrical losses in interconnection transformers	kW
7d Electrical losses in AC/DC conversion equipment, if any	kW
7e Other interconnection losses in power lines or facilities (other than transformers) between the terminals of the generator(s) and the point of interconnection with the utility	kW
7f Total deductions from gross power production capacity = 7b + 7c + 7d + 7e	kW
7g Maximum net power production capacity = 7a - 7f	kW

7h Description of facility and primary components: Describe the facility and its operation. Identify all boilers, heat recovery steam generators, prime movers (any mechanical equipment driving an electric generator), electrical generators, photovoltaic solar equipment, fuel cell equipment and/or other primary power generation equipment used in the facility. Descriptions of components should include (as applicable) specifications of the nominal capacities for mechanical output, electrical output, or steam generation of the identified equipment. For each piece of equipment identified, clearly indicate how many pieces of that type of equipment are included in the plant, and which components are normally operating or normally in standby mode. Provide a description of how the components operate as a system. Applicants for cogeneration facilities do not need to describe operations of systems that are clearly depicted on and easily understandable from a cogeneration facility's attached mass and heat balance diagram; however, such applicants should provide any necessary description needed to understand the sequential operation of the facility depicted in their mass and heat balance diagram. If additional space is needed, continue in the Miscellaneous section starting on page 19.

Information Required for Small Power Production Facility

If you indicated in line 1k that you are seeking qualifying small power production facility status for your facility, then you must respond to the items on this page. Otherwise, skip page 10.

Certification of Compliance with Size Limitations	Pursuant to 18 C.F.R. § 292.204(a), the power production capacity of any small power production facility, together with the power production capacity of any other small power production facilities that use the same energy resource, are owned by the same person(s) or its affiliates, and are located at the same site, may not exceed 80 megawatts. To demonstrate compliance with this size limitation, or to demonstrate that your facility is exempt from this size limitation under the Solar, Wind, Waste, and Geothermal Power Production Incentives Act of 1990 (Pub. L. 101-575, 104 Stat. 2834 (1990) <i>as amended by</i> Pub. L. 102-46, 105 Stat. 249 (1991)), respond to lines 8a through 8d below (as applicable).																
	8a Was the original notice of self-certification or application for Commission certification of the facility filed on or before December 31, 1994? Yes <input type="checkbox"/> No <input type="checkbox"/>																
	8b Did construction of the facility commence on or before December 31, 1999? Yes <input type="checkbox"/> No <input type="checkbox"/>																
	8c If you answered No in line 8b, was reasonable diligence exercised toward the completion of the facility, taking into account all factors relevant to construction? Yes <input type="checkbox"/> No <input type="checkbox"/> If you answered Yes in line 8c, provide a brief narrative explanation in the Miscellaneous section starting on page 19 of the construction timeline (in particular, describe why construction started so long after the facility was certified) and the diligence exercised toward completion of the facility.																
	If any of the answers to lines 8a, 8b or 8c is No, then you must complete line 8d; otherwise, skip line 8d.																
Certification of Compliance with Fossil Fuel Use Requirements	8d Identify any facilities with electrical generating equipment located within 1 mile of the electrical generating equipment of the instant facility, and for which any of the entities identified in lines 5a or 5b, or their affiliates, holds at least a 5 percent equity interest. Enter "None" at the first line if no such facilities exist.																
	<table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 35%; text-align: left; border-bottom: 1px solid black;">Facility name (if any)</th> <th style="width: 15%; text-align: left; border-bottom: 1px solid black;">Root docket #</th> <th style="width: 35%; text-align: left; border-bottom: 1px solid black;">Common owner(s)</th> <th style="width: 15%; text-align: right; border-bottom: 1px solid black;">Maximum net power production capacity</th> </tr> </thead> <tbody> <tr> <td>1) _____</td> <td>QF - _____</td> <td>_____</td> <td style="text-align: right;">_____ kW</td> </tr> <tr> <td>2) _____</td> <td>QF - _____</td> <td>_____</td> <td style="text-align: right;">_____ kW</td> </tr> <tr> <td>3) _____</td> <td>QF - _____</td> <td>_____</td> <td style="text-align: right;">_____ kW</td> </tr> </tbody> </table>	Facility name (if any)	Root docket #	Common owner(s)	Maximum net power production capacity	1) _____	QF - _____	_____	_____ kW	2) _____	QF - _____	_____	_____ kW	3) _____	QF - _____	_____	_____ kW
	Facility name (if any)	Root docket #	Common owner(s)	Maximum net power production capacity													
	1) _____	QF - _____	_____	_____ kW													
	2) _____	QF - _____	_____	_____ kW													
3) _____	QF - _____	_____	_____ kW														
<input type="checkbox"/> Check here and continue in the Miscellaneous section starting on page 19 if additional space is needed																	
Pursuant to 18 C.F.R. § 292.204(b), qualifying small power production facilities may use fossil fuels, in minimal amounts, for only the following purposes: ignition; start-up; testing; flame stabilization; control use; alleviation or prevention of unanticipated equipment outages; and alleviation or prevention of emergencies, directly affecting the public health, safety, or welfare, which would result from electric power outages. The amount of fossil fuels used for these purposes may not exceed 25 percent of the total energy input of the facility during the 12-month period beginning with the date the facility first produces electric energy or any calendar year thereafter.																	
9a Certification of compliance with 18 C.F.R. § 292.204(b) with respect to uses of fossil fuel: <input type="checkbox"/> Applicant certifies that the facility will use fossil fuels <u>exclusively</u> for the purposes listed above.																	
9b Certification of compliance with 18 C.F.R. § 292.204(b) with respect to amount of fossil fuel used annually: <input type="checkbox"/> Applicant certifies that the amount of fossil fuel used at the facility will not, in aggregate, exceed 25 percent of the total energy input of the facility during the 12-month period beginning with the date the facility first produces electric energy or any calendar year thereafter.																	

Information Required for Cogeneration Facility

If you indicated in line 1k that you are seeking qualifying cogeneration facility status for your facility, then you must respond to the items on pages 11 through 13. Otherwise, skip pages 11 through 13.

General Cogeneration Information	<p>Pursuant to 18 C.F.R. § 292.202(c), a cogeneration facility produces electric energy and forms of useful thermal energy (such as heat or steam) used for industrial, commercial, heating, or cooling purposes, through the sequential use of energy. Pursuant to 18 C.F.R. § 292.202(s), "sequential use" of energy means the following: (1) for a topping-cycle cogeneration facility, the use of reject heat from a power production process in sufficient amounts in a thermal application or process to conform to the requirements of the operating standard contained in 18 C.F.R. § 292.205(a); or (2) for a bottoming-cycle cogeneration facility, the use of at least some reject heat from a thermal application or process for power production.</p>																		
	<p>10a What type(s) of cogeneration technology does the facility represent? (check all that apply)</p> <p style="text-align: center;"> <input type="checkbox"/> Topping-cycle cogeneration <input type="checkbox"/> Bottoming-cycle cogeneration </p>																		
	<p>10b To help demonstrate the sequential operation of the cogeneration process, and to support compliance with other requirements such as the operating and efficiency standards, include with your filing a mass and heat balance diagram depicting average annual operating conditions. This diagram must include certain items and meet certain requirements, as described below. You must check next to the description of each requirement below to certify that you have complied with these requirements.</p>																		
	<table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 25%; text-align: center; border-bottom: 1px solid black;">Check to certify compliance with indicated requirement</th> <th style="text-align: center; border-bottom: 1px solid black;">Requirement</th> </tr> </thead> <tbody> <tr> <td style="text-align: center; vertical-align: top;"><input type="checkbox"/></td> <td>Diagram must show orientation within system piping and/or ducts of all prime movers, heat recovery steam generators, boilers, electric generators, and condensers (as applicable), as well as any other primary equipment relevant to the cogeneration process.</td> </tr> <tr> <td style="text-align: center; vertical-align: top;"><input type="checkbox"/></td> <td>Diagram must specify all fuel inputs by fuel type and average annual rate in Btu/h. Fuel for supplementary firing should be specified separately and clearly labeled. 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Exception: For systems where the working fluid is <u>liquid only</u> (no vapor at any point in the cycle) and where the type of liquid and specific heat of that liquid are clearly indicated on the diagram or in the Miscellaneous section starting on page 19, only mass flow rate and temperature (not pressure and enthalpy) need be specified. For reference, specific heat at standard conditions for pure liquid water is approximately 1.002 Btu/(lb*R) or 4.195 kJ/(kg*K).</td> </tr> <tr> <td style="text-align: center; vertical-align: top;"><input type="checkbox"/></td> <td>Diagram must specify working fluid flow conditions at input to and output from each steam turbine or other expansion turbine or back-pressure turbine.</td> </tr> <tr> <td style="text-align: center; vertical-align: top;"><input type="checkbox"/></td> <td>Diagram must specify working fluid flow conditions at delivery to and return from each thermal application.</td> </tr> <tr> <td style="text-align: center; vertical-align: top;"><input type="checkbox"/></td> <td>Diagram must specify working fluid flow conditions at make-up water inputs.</td> </tr> </tbody> </table>	Check to certify compliance with indicated requirement	Requirement	<input type="checkbox"/>	Diagram must show orientation within system piping and/or ducts of all prime movers, heat recovery steam generators, boilers, electric generators, and condensers (as applicable), as well as any other primary equipment relevant to the cogeneration process.	<input type="checkbox"/>	Diagram must specify all fuel inputs by fuel type and average annual rate in Btu/h. 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FERC Form 556

Cogeneration Facilities

EPAAct 2005 Requirements for Fundamental Use of Energy Output from Cogeneration Facilities

EPAAct 2005 cogeneration facilities: The Energy Policy Act of 2005 (EPAAct 2005) established a new section 210(n) of the Public Utility Regulatory Policies Act of 1978 (PURPA), 16 USC 824a-3(n), with additional requirements for any qualifying cogeneration facility that (1) is seeking to sell electric energy pursuant to section 210 of PURPA and (2) was either not a cogeneration facility on August 8, 2005, or had not filed a self-certification or application for Commission certification of QF status on or before February 1, 2006. These requirements were implemented by the Commission in 18 C.F.R. § 292.205(d). Complete the lines below, carefully following the instructions, to demonstrate whether these additional requirements apply to your cogeneration facility and, if so, whether your facility complies with such requirements.

11a Was your facility operating as a qualifying cogeneration facility on or before August 8, 2005? Yes No

11b Was the initial filing seeking certification of your facility (whether a notice of self-certification or an application for Commission certification) filed on or before February 1, 2006? Yes No

If the answer to either line 11a or 11b is Yes, then continue at line 11c below. Otherwise, if the answers to both lines 11a and 11b are No, skip to line 11e below.

11c With respect to the design and operation of the facility, have any changes been implemented on or after February 2, 2006 that affect general plant operation, affect use of thermal output, and/or increase net power production capacity from the plant's capacity on February 1, 2006?

Yes (continue at line 11d below)

No. Your facility is not subject to the requirements of 18 C.F.R. § 292.205(d) at this time. However, it may be subject to these requirements in the future if changes are made to the facility. At such time, the applicant would need to recertify the facility to determine eligibility. Skip lines 11d through 11k.

11d Does the applicant contend that the changes identified in line 11c are not so significant as to make the facility a "new" cogeneration facility that would be subject to the 18 C.F.R. § 292.205(d) cogeneration requirements?

Yes. Provide in the Miscellaneous section starting on page 19 a description of any relevant changes made to the facility (including the purpose of the changes) and a discussion of why the facility should not be considered a "new" cogeneration facility in light of these changes. Skip lines 11e through 11j.

No. Applicant stipulates to the fact that it is a "new" cogeneration facility (for purposes of determining the applicability of the requirements of 18 C.F.R. § 292.205(d)) by virtue of modifications to the facility that were initiated on or after February 2, 2006. Continue below at line 11e.

11e Will electric energy from the facility be sold pursuant to section 210 of PURPA?

Yes. The facility is an EPAAct 2005 cogeneration facility. You must demonstrate compliance with 18 C.F.R. § 292.205(d)(2) by continuing at line 11f below.

No. Applicant certifies that energy will not be sold pursuant to section 210 of PURPA. Applicant also certifies its understanding that it must recertify its facility in order to determine compliance with the requirements of 18 C.F.R. § 292.205(d) before selling energy pursuant to section 210 of PURPA in the future. Skip lines 11f through 11j.

11f Is the net power production capacity of your cogeneration facility, as indicated in line 7g above, less than or equal to 5,000 kW?

Yes, the net power production capacity is less than or equal to 5,000 kW. 18 C.F.R. § 292.205(d)(4) provides a rebuttable presumption that cogeneration facilities of 5,000 kW and smaller capacity comply with the requirements for fundamental use of the facility's energy output in 18 C.F.R. § 292.205(d)(2). Applicant certifies its understanding that, should the power production capacity of the facility increase above 5,000 kW, then the facility must be recertified to (among other things) demonstrate compliance with 18 C.F.R. § 292.205(d)(2). Skip lines 11g through 11j.

No, the net power production capacity is greater than 5,000 kW. Demonstrate compliance with the requirements for fundamental use of the facility's energy output in 18 C.F.R. § 292.205(d)(2) by continuing on the next page at line 11g.

FERC Form 556

Cogeneration Facilities

EPAAct 2005 Requirements for Fundamental Use of Energy Output from Cogeneration Facilities (continued)

Lines 11g through 11k below guide the applicant through the process of demonstrating compliance with the requirements for "fundamental use" of the facility's energy output. 18 C.F.R. § 292.205(d)(2). Only respond to the lines on this page if the instructions on the previous page direct you to do so. Otherwise, skip this page.

18 C.F.R. § 292.205(d)(2) requires that the electrical, thermal, chemical and mechanical output of an EPAAct 2005 cogeneration facility is used fundamentally for industrial, commercial, residential or institutional purposes and is not intended fundamentally for sale to an electric utility, taking into account technological, efficiency, economic, and variable thermal energy requirements, as well as state laws applicable to sales of electric energy from a qualifying facility to its host facility. If you were directed on the previous page to respond to the items on this page, then your facility is an EPAAct 2005 cogeneration facility that is subject to this "fundamental use" requirement.

The Commission's regulations provide a two-pronged approach to demonstrating compliance with the requirements for fundamental use of the facility's energy output. First, the Commission has established in 18 C.F.R. § 292.205(d)(3) a "fundamental use test" that can be used to demonstrate compliance with 18 C.F.R. § 292.205(d)(2). Under the fundamental use test, a facility is considered to comply with 18 C.F.R. § 292.205(d)(2) if at least 50 percent of the facility's total annual energy output (including electrical, thermal, chemical and mechanical energy output) is used for industrial, commercial, residential or institutional purposes.

Second, an applicant for a facility that does not pass the fundamental use test may provide a narrative explanation of and support for its contention that the facility nonetheless meets the requirement that the electrical, thermal, chemical and mechanical output of an EPAAct 2005 cogeneration facility is used fundamentally for industrial, commercial, residential or institutional purposes and is not intended fundamentally for sale to an electric utility, taking into account technological, efficiency, economic, and variable thermal energy requirements, as well as state laws applicable to sales of electric energy from a qualifying facility to its host facility.

Complete lines 11g through 11j below to determine compliance with the fundamental use test in 18 C.F.R. § 292.205(d)(3). Complete lines 11g through 11j even if you do not intend to rely upon the fundamental use test to demonstrate compliance with 18 C.F.R. § 292.205(d)(2).

11g Amount of electrical, thermal, chemical and mechanical energy output (net of internal generation plant losses and parasitic loads) expected to be used annually for industrial, commercial, residential or institutional purposes and not sold to an electric utility	MWh
11h Total amount of electrical, thermal, chemical and mechanical energy expected to be sold to an electric utility	MWh
11i Percentage of total annual energy output expected to be used for industrial, commercial, residential or institutional purposes and not sold to a utility = $100 * 11g / (11g + 11h)$	%

11j Is the response in line 11i greater than or equal to 50 percent?

Yes. Your facility complies with 18 C.F.R. § 292.205(d)(2) by virtue of passing the fundamental use test provided in 18 C.F.R. § 292.205(d)(3). Applicant certifies its understanding that, if it is to rely upon passing

the fundamental use test as a basis for complying with 18 C.F.R. § 292.205(d)(2), then the facility must comply with the fundamental use test both in the 12-month period beginning with the date the facility first produces electric energy, and in all subsequent calendar years.

No. Your facility does not pass the fundamental use test. Instead, you must provide in the Miscellaneous section starting on page 19 a narrative explanation of and support for why your facility meets the requirement that the electrical, thermal, chemical and mechanical output of an EPAAct 2005 cogeneration facility is used fundamentally for industrial, commercial, residential or institutional purposes and is not intended fundamentally for sale to an electric utility, taking into account technological, efficiency, economic, and variable thermal energy requirements, as well as state laws applicable to sales of electric energy from a QF to its host facility. Applicants providing a narrative explanation of why their facility should be found to

comply with 18 C.F.R. § 292.205(d)(2) in spite of non-compliance with the fundamental use test may want to review paragraphs 47 through 61 of Order No. 671 (accessible from the Commission's QF website at www.ferc.gov/QF), which provide discussion of the facts and circumstances that may support their explanation. Applicant should also note that the percentage reported above will establish the standard that that facility must comply with, both for the 12-month period beginning with the date the facility first produces electric energy, and in all subsequent calendar years. See Order No. 671 at paragraph 51. As such, the applicant should make sure that it reports appropriate values on lines 11g and 11h above to serve as the relevant annual standard, taking into account expected variations in production conditions.

Information Required for Topping-Cycle Cogeneration Facility

If you indicated in line 10a that your facility represents topping-cycle cogeneration technology, then you must respond to the items on pages 14 and 15. Otherwise, skip pages 14 and 15.

Usefulness of Topping-Cycle Thermal Output	<p>The thermal energy output of a topping-cycle cogeneration facility is the net energy made available to an industrial or commercial process or used in a heating or cooling application. Pursuant to sections 292.202(c), (d) and (h) of the Commission's regulations (18 C.F.R. §§ 292.202(c), (d) and (h)), the thermal energy output of a qualifying topping-cycle cogeneration facility must be useful. In connection with this requirement, describe the thermal output of the topping-cycle cogeneration facility by responding to lines 12a and 12b below.</p>		
	<p>12a Identify and describe each thermal host, and specify the annual average rate of thermal output made available to each host for each use. For hosts with multiple uses of thermal output, provide the data for each use <u>in separate rows</u>.</p>		
	Name of entity (thermal host) taking thermal output	Thermal host's relationship to facility; Thermal host's use of thermal output	Average annual rate of thermal output attributable to use (net of heat contained in process return or make-up water)
	1)		Btu/h
	2)		Btu/h
	3)		Btu/h
	4)		Btu/h
	5)		Btu/h
	6)		Btu/h
	<input type="checkbox"/> Check here and continue in the Miscellaneous section starting on page 19 if additional space is needed		
<p>12b Demonstration of usefulness of thermal output: At a minimum, provide a brief description of each use of the thermal output identified above. In some cases, this brief description is sufficient to demonstrate usefulness. However, if your facility's use of thermal output is not common, and/or if the usefulness of such thermal output is not reasonably clear, then you must provide additional details as necessary to demonstrate usefulness. Your application may be rejected and/or additional information may be required if an insufficient showing of usefulness is made. (Exception: If you have previously received a Commission certification approving a specific use of thermal output related to the instant facility, then you need only provide a brief description of that use and a reference by date and docket number to the order certifying your facility with the indicated use. Such exemption may not be used if any change creates a material deviation from the previously authorized use.) If additional space is needed, continue in the Miscellaneous section starting on page 19.</p>			

FERC Form 556

Topping-Cycle Cogeneration Facilities

Topping-Cycle Operating and Efficiency Value Calculation

Applicants for facilities representing topping-cycle technology must demonstrate compliance with the topping-cycle operating and efficiency standards. Section 292.205(a)(1) of the Commission's regulations (18 C.F.R. § 292.205(a)(1)) establishes the operating standard for topping-cycle cogeneration facilities: the useful thermal energy output must be no less than 5 percent of the total energy output. Section 292.205(a)(2) (18 C.F.R. § 292.205(a)(2)) establishes the efficiency standard for topping-cycle cogeneration facilities: the useful power output of the facility plus one-half the useful thermal energy output must (A) be no less than 42.5 percent of the total energy input of natural gas and oil to the facility; and (B) if the useful thermal energy output is less than 15 percent of the total energy output of the facility, be no less than 45 percent of the total energy input of natural gas and oil to the facility. To demonstrate compliance with the topping-cycle operating and efficiency standards, or to demonstrate that your facility is exempt from these standards based on the date that installation began, respond to lines 13a through 13l below.

If you indicated in line 10a that your facility represents both topping-cycle and bottoming-cycle cogeneration technology, then respond to lines 13a through 13l below considering only the energy inputs and outputs attributable to the topping-cycle portion of your facility. Your mass and heat balance diagram must make clear which mass and energy flow values and system components are for which portion (topping or bottoming) of the cogeneration system.

13a Did installation of the facility commence on or after March 13, 1980? Yes No

If you answered Yes in line 13a, then you must complete lines 13b through 13l. If you answered No, then your facility is exempt from the operating and efficiency standards, and you should skip the rest of page 15.

13b Indicate the annual average rate of useful thermal energy output made available to the host(s), net of any heat contained in condensate return or make-up water Btu/h

13c Indicate the annual average rate of net electrical energy output kW

13d Multiply line 13c by 3,412 to convert from kW to Btu/h Btu/h

13e Indicate the annual average rate of mechanical energy output taken directly off of the shaft of a prime mover for purposes not directly related to power production (this value is usually zero) hp

13f Multiply line 13e by 2,544 to convert from hp to Btu/h Btu/h

13g Indicate the annual average rate of energy input from natural gas and oil Btu/h

13h Topping-cycle operating value = $100 * 13b / (13b + 13d + 13f)$ %

13i Topping-cycle efficiency value = $100 * (0.5 * 13b + 13d + 13f) / 13g$ %

13j Compliance with operating standard: Is the operating value shown in line 13i greater than or equal to 5%?
 Yes (complies with operating standard) No (does not comply with operating standard)

13k Compliance with efficiency standard (for low operating value): If the operating value shown in line 13i is less than 15%, then indicate below whether the efficiency value shown in line 13j greater than or equal to 45%:
 Yes (complies with efficiency standard) No (does not comply with efficiency standard) N/A

13l Compliance with efficiency standard (for high operating value): If the operating value shown in line 13i is greater than or equal to 15%, then indicate below whether the efficiency value shown in line 13j is greater than or equal to 42.5%:
 Yes (complies with efficiency standard) No (does not comply with efficiency standard) N/A

Information Required for Bottoming-Cycle Cogeneration Facility

If you indicated in line 10a that your facility represents bottoming-cycle cogeneration technology, then you must respond to the items on pages 16 and 17. Otherwise, skip pages 16 and 17.

Usefulness of Bottoming-Cycle Thermal Output	The thermal energy output of a bottoming-cycle cogeneration facility is the energy related to the process(es) from which at least some of the reject heat is then used for power production. Pursuant to sections 292.202(c) and (e) of the Commission's regulations (18 C.F.R. § 292.202(c) and (e)), the thermal energy output of a qualifying bottoming-cycle cogeneration facility must be useful. In connection with this requirement, describe the process(es) from which at least some of the reject heat is used for power production by responding to lines 14a and 14b below.		
	14a Identify and describe each thermal host and each bottoming-cycle cogeneration process engaged in by each host. For hosts with multiple bottoming-cycle cogeneration processes, provide the data for each process <u>in separate rows</u> .		
		Name of entity (thermal host) performing the process from which at least some of the reject heat is used for power production	Thermal host's relationship to facility; Thermal host's process type
			Has the energy input to the thermal host been augmented for purposes of increasing power production capacity? (if yes, describe on page 19)
	1)		Yes <input type="checkbox"/> No <input type="checkbox"/>
2)		Yes <input type="checkbox"/> No <input type="checkbox"/>	
3)		Yes <input type="checkbox"/> No <input type="checkbox"/>	
<input type="checkbox"/> Check here and continue in the Miscellaneous section starting on page 19 if additional space is needed			
14b Demonstration of usefulness of thermal output: At a minimum, provide a brief description of each process identified above. In some cases, this brief description is sufficient to demonstrate usefulness. However, if your facility's process is not common, and/or if the usefulness of such thermal output is not reasonably clear, then you must provide additional details as necessary to demonstrate usefulness. Your application may be rejected and/or additional information may be required if an insufficient showing of usefulness is made. (Exception: If you have previously received a Commission certification approving a specific bottoming-cycle process related to the instant facility, then you need only provide a brief description of that process and a reference by date and docket number to the order certifying your facility with the indicated process. Such exemption may not be used if any material changes to the process have been made.) If additional space is needed, continue in the Miscellaneous section starting on page 19.			

FERC Form 556

Bottoming-Cycle Cogeneration Facilities

Bottoming-Cycle Operating and Efficiency Value Calculation	<p>Applicants for facilities representing bottoming-cycle technology must demonstrate compliance with the bottoming-cycle operating and efficiency standards. Section 292.205(b) of the Commission's regulations (18 C.F.R. § 292.205(b)) establishes the efficiency standard for bottoming-cycle cogeneration facilities: the useful power output of the facility must be no less than 45 percent of the energy input of natural gas and oil for supplementary firing. To demonstrate compliance with the bottoming-cycle efficiency standard (if applicable), or to demonstrate that your facility is exempt from this standard based on the date that installation of the facility began, respond to lines 15a through 15h below.</p> <p>If you indicated in line 10a that your facility represents <u>both</u> topping-cycle and bottoming-cycle cogeneration technology, then respond to lines 15a through 15h below considering only the energy inputs and outputs attributable to the bottoming-cycle portion of your facility. Your mass and heat balance diagram must make clear which mass and energy flow values and system components are for which portion of the cogeneration system (topping or bottoming).</p>	
	<p>15a Did installation of the facility commence on or after March 13, 1980? Yes <input type="checkbox"/> No <input type="checkbox"/></p>	
	<p>If you answered Yes in line 15a, then you must complete lines 15b through 15h. If you answered No, then your facility is exempt from the efficiency standard, and you should skip the rest of page 17.</p>	
	<p>15b Indicate the annual average rate of net electrical energy output</p>	kW
	<p>15c Multiply line 15b by 3,412 to convert from kW to Btu/h</p>	Btu/h
	<p>15d Indicate the annual average rate of mechanical energy output taken directly off of the shaft of a prime mover for purposes not directly related to power production (this value is usually zero)</p>	hp
	<p>15e Multiply line 15d by 2,544 to convert from hp to Btu/h</p>	Btu/h
	<p>15f Indicate the annual average rate of supplementary energy input from natural gas or oil</p>	Btu/h
	<p>15g Bottoming-cycle efficiency value = $100 * (15c + 15e) / 15f$</p>	%
	<p>15h Compliance with efficiency standard: Indicate below whether the efficiency value shown in line 15g is greater than or equal to 45%:</p> <p><input type="checkbox"/> Yes (complies with efficiency standard) <input type="checkbox"/> No (does not comply with efficiency standard)</p>	

Certificate of Completeness, Accuracy and Authority

Applicant must certify compliance with and understanding of filing requirements by checking next to each item below and signing at the bottom of this section. Forms with incomplete Certificates of Completeness, Accuracy and Authority will be rejected by the Secretary of the Commission.

Signer identified below certifies the following: (check all items and applicable subitems)

He or she has read the filing, including any information contained in any attached documents, such as cogeneration mass and heat balance diagrams, and any information contained in the Miscellaneous section starting on page 19, and knows its contents.

He or she has provided all of the required information for certification, and the provided information is true as stated, to the best of his or her knowledge and belief.

He or she possess full power and authority to sign the filing; as required by Rule 2005(a)(3) of the Commission's Rules of Practice and Procedure (18 C.F.R. § 385.2005(a)(3)), he or she is one of the following: (check one)

The person on whose behalf the filing is made

An officer of the corporation, trust, association, or other organized group on behalf of which the filing is made

An officer, agent, or employe of the governmental authority, agency, or instrumentality on behalf of which the filing is made

A representative qualified to practice before the Commission under Rule 2101 of the Commission's Rules of Practice and Procedure (18 C.F.R. § 385.2101) and who possesses authority to sign

He or she has reviewed all automatic calculations and agrees with their results, unless otherwise noted in the Miscellaneous section starting on page 19.

He or she has provided a copy of this Form 556 and all attachments to the utilities with which the facility will interconnect and transact (see lines 4a through 4d), as well as to the regulatory authorities of the states in which the facility and those utilities reside. See the Required Notice to Public Utilities and State Regulatory Authorities section on page 3 for more information.

Provide your signature, address and signature date below. Rule 2005(c) of the Commission's Rules of Practice and Procedure (18 C.F.R. § 385.2005(c)) provides that persons filing their documents electronically may use typed characters representing his or her name to sign the filed documents. A person filing this document electronically should sign (by typing his or her name) in the space provided below.

Your Signature

Your address

Date

Audit Notes

Commission Staff Use Only:

FERC Form 556

All Facilities

Miscellaneous

Use this space to provide any information for which there was not sufficient space in the previous sections of the form to provide. For each such item of information clearly identify the line number that the information belongs to. You may also use this space to provide any additional information you believe is relevant to the certification of your facility.

Your response below is not limited to one page. Additional page(s) will automatically be inserted into this form if the length of your response exceeds the space on this page. Use as many pages as you require.

[FR Doc. E9-25261 Filed 10-21-09; 8:45 am]
BILLING CODE 6717-01-C

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 151

46 CFR Part 162

[USCG-2001-10486]

RIN 1625-AA32

Standards for Living Organisms in Ships' Ballast Water Discharged in U.S. Waters

AGENCY: Coast Guard, DHS.

ACTION: Notice of public meetings.

SUMMARY: This notice provides the times and locations of two public meetings which will be held by the Coast Guard (USCG) regarding the Notice of Proposed Rulemaking (NPRM) entitled "Standards for Living Organisms in Ships' Ballast Water Discharged in U.S. Waters" that published in the **Federal Register** on Friday, August 28, 2009.

DATES: Public meetings will be held in the Oakland, CA (October 27, 2009) and New York, NY (October 29, 2009) areas to provide opportunities for oral comments. The comment period for the NPRM closes on December 4, 2009. All comments and related material submitted after a meeting must either be submitted to our online docket via <http://www.regulations.gov> on or before December 4, 2009 or reach the Docket Management Facility by that date.

ADDRESSES: The public meetings will be held at the Marriott Oakland City Center, 1001 Broadway, Oakland, CA, 94607, on October 27, 2009, and the Marriott New York Downtown, 85 West Street at Albany Street, New York, NY 10006, on October 29, 2009.

All meetings will be held from 9 a.m. until 4 p.m. local time unless otherwise noted. The meetings may conclude before the allotted time if all matters of discussion have been addressed.

You may submit written comments identified by docket number USCG-2001-10486 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 rulemaking is available on the Internet at <http://www.regulations.gov> under docket number USCG-2001-10486.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rulemaking, call or e-mail Mr. John Morris, Project Manager, Environmental Standards Division, U.S. Coast Guard Headquarters, telephone 202-372-1433, e-mail: John.C.Morris@uscg.mil. If you have questions on viewing or submitting material to the docket, call Ms. Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:

The Coast Guard published a Notice of Proposed Rulemaking (NPRM) in the **Federal Register** on Friday, August 28, 2009 (74 FR 44632), entitled "Standards for Living Organisms in Ships' Ballast Water Discharged in U.S. Waters." In it, we stated our intention to hold public meetings, and to publish a notice with additional details regarding those public meetings as soon as the information was available (74 FR 44632).

On Monday, September 14, 2009, we published a Notice of Public Meeting to inform the public of the date for each public meeting, as well as the city in which those meetings will be held (74 FR 46964). That notice also stated that additional notice(s) would be published in the **Federal Register** as specific

locations and details for these meetings were finalized.

On Tuesday, September 22, 2009, we published a Notice of Public Meeting with the specific locations and details for the first two of the six public meetings (74 FR 48190). Then, on Monday, September 28, 2009, we published a Notice of Public Meeting providing the same information for the second two public meetings and restating the details for the first two public meetings (74 FR 49355). This notice provides those details for the final two public meetings.

On Thursday, October 15, 2009, we published a Notice to extend the periods of public comment on the Notice of Proposed Rulemaking (NPRM) and the Draft Programmatic Environmental Impact Statement (DPEIS) to December 4, 2009 (74 FR 52941).

The October 27, 2009 meeting will be held at the Marriott Oakland City Center, 1001 Broadway, Oakland, CA, 94607. The phone number for the location is 510-451-4000.

The October 29, 2009 meeting will be held at the Marriott New York Downtown, 85 West Street at Albany Street, New York, NY 10006. The phone number for the location is 212-385-4900.

Live webcasts (audio and video) of the public meetings will also be broadcast online at <http://ballastwater.us/>.

Written comments and related material may also be submitted to Coast Guard personnel specified at those meetings for inclusion in the official docket for this rulemaking.

Information on Service for Individuals With Disabilities

For information on facilities or services for individuals with disabilities or to request special assistance at the public meetings, contact Mr. John Morris at the telephone number or e-mail address indicated under the **FOR FURTHER INFORMATION CONTACT** section of this notice.

Dated: October 19, 2009.

F.J. Sturm,

Acting Director of Commercial Regulations and Standards, U.S. Coast Guard.

[FR Doc. E9-25558 Filed 10-20-09; 4:15 pm]

BILLING CODE 4910-15-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R03-OAR-2009-0599; FRL-8971-5]

Approval and Promulgation of Air Quality Implementation Plans; Virginia; Revision to Clean Air Interstate Rule Sulfur Dioxide Trading Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve the State Implementation Plan (SIP) revision submitted by the Commonwealth of Virginia for the purpose of changing the timing of the first phase of the sulfur dioxide (SO₂) trading budget under the Commonwealth's approved regulations that implement the requirements of the Clean Air Interstate Rule (CAIR). In the Final Rules section of this **Federal Register**, EPA is approving the Commonwealth's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this action, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time.

DATES: Comments must be received in writing by November 23, 2009.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA-R03-OAR-2009-0599 by one of the following methods:

A. *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.

B. *E-mail:* fernandez.cristina@epa.gov.

C. *Mail:* EPA-R03-OAR-2009-0599, Cristina Fernandez, Chief, Air Quality Planning Branch, Mailcode 3AP21, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. *Hand Delivery:* At the previously-listed EPA Region III address. 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-R03-OAR-2009-0599. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. The *http://www.regulations.gov* Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://www.regulations.gov*, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your

name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the Virginia Department of Environmental Quality, 629 East Main Street, Richmond, Virginia 23219.

FOR FURTHER INFORMATION CONTACT: Marilyn Powers, (215) 814-2308, or by e-mail at *powers.marilyn@epa.gov*.

SUPPLEMENTARY INFORMATION: For further information, please see the information provided in the direct final action for the approval of the Virginia revision to the CAIR SO₂ trading program, with the same title, that is located in the "Rules and Regulations" section of this **Federal Register** publication.

Dated: October 13, 2009.

James W. Newsom,

Acting Regional Administrator, Region III.

[FR Doc. E9-25353 Filed 10-21-09; 8:45 am]

BILLING CODE 6560-50-P

Notices

Federal Register

Vol. 74, No. 203

Thursday, October 22, 2009

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Forest Service

North Central Idaho Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The North Central Idaho RAC will meet in Grangeville, Idaho. The committee is meeting as authorized under the Secure Rural Schools and Community Self Determination Act (Pub. L. 110-343) and in compliance with the Federal Advisory Committee Act. The purpose of the meeting is to discuss potential projects for the new fiscal year.

DATES: The meeting will be held November 12, 2009 at 10 a.m. (PST).

ADDRESSES: The meeting will be held at Nez Perce National Forest Supervisor's Office, 104 Airport Road in Grangeville. Written comments should be sent to Laura Smith at 104 Airport Road in Grangeville, Idaho 83530. Comments may also be sent via e-mail to lasmith@fs.fed.us or via facsimile to Laura at 208-983-4099.

FOR FURTHER INFORMATION CONTACT: Laura Smith, Designated Forest Official at 208-983-5143.

SUPPLEMENTARY INFORMATION: The meeting is open to the public. A public forum will begin at 3:15 p.m. (PST). The following business will be conducted: discussion of project for FY10 and project updates. Persons who wish to bring related matters to the attention of the Committee may file written statements with the Committee staff before or after the meeting.

Dated: October 14, 2009.

Rick Brazell,

Forest Supervisor.

[FR Doc. E9-25301 Filed 10-21-09; 8:45 am]

BILLING CODE 3410-11-M

COMMISSION ON CIVIL RIGHTS

Sunshine Act Notice

AGENCY: United States Commission on Civil Rights.

ACTION: Notice of meeting.

DATE AND TIME: Friday, October 30, 2009; 11:30 a.m. EDT.

PLACE: Via Teleconference, Public Dial In—1-800-597-7623, Conference ID # 36220517.

Meeting Agenda

This meeting is open to the public.

- I. Approval of Agenda.
- II. Approval of Minutes of September 3, September 11, September 24, October 8 and October 16 Meetings.
- III. Management and Operations.
 - Approval of Calendar of 2010 Commission Meetings.
- IV. Program Planning.
 - Update on Proposed Hearings for FY 2010 Enforcement Report.
 - Update on FY 2010 Project on Sex Discrimination in Higher Education Admissions.
- V. Adjourn.

CONTACT PERSON FOR FURTHER

INFORMATION: Lenore Ostrowsky, Acting Chief, Public Affairs Unit, (202) 376-8582. TDD: (202) 376-8116.

Persons with a disability requiring special services, such as an interpreter for the hearing impaired, should contact Pamela Dunston at least seven days prior to the meeting at 202-376-8105. TDD: (202) 376-8116.

Dated: October 20, 2009.

David Blackwood,

General Counsel.

[FR Doc. E9-25574 Filed 10-20-09; 4:15 pm]

BILLING CODE 6335-01-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-570-947]

Certain Steel Grating from the People's Republic of China: Postponement of Preliminary Determination of Antidumping Duty Investigation

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: October 22, 2009.

FOR FURTHER INFORMATION CONTACT:

Thomas Martin or Zhulieta Willbrand, AD/CVD Operations, Office 4, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230; telephone: (202) 482-3936 or (202) 482-3147, respectively.

SUPPLEMENTARY INFORMATION:

Postponement of Preliminary Determination

On June 25, 2009, the Department of Commerce ("the Department") initiated an antidumping duty investigation on certain steel grating from the People's Republic of China.¹ The notice of initiation stated that, unless postponed, the Department would issue its preliminary determination no later than 140 days after the date of issuance of the initiation, in accordance with section 733(b)(1)(A) of the Tariff Act of 1930, as amended ("the Act"). The preliminary determination is currently due no later than November 5, 2009.

As discussed below, we have determined that this investigation is extraordinarily complicated within the meaning of section 733(c)(1)(B)(i)(II) of the Act. Furthermore, we have determined that the parties concerned are cooperating, as required by section 733(c)(1)(B) of the Act, and that additional time is necessary to make this preliminary determination in accordance with section 733(c)(1)(B)(ii) of the Act.

In the investigation of certain steel grating, one of the respondents has submitted a novel reporting methodology for its U.S. sales, and the Department may require additional information from the respondent in order to obtain complete and appropriate data on the record to calculate an accurate dumping margin with respect to the respondent's U.S. sales. The Department can only complete its analysis and gather all of the necessary information by postponing the preliminary determination. Therefore, it is the Department's decision to postpone the current preliminary determination so that all of the issues currently under investigation at this time can be

¹ See *Certain Steel Grating from the People's Republic of China: Initiation of Antidumping Duty Investigation*, 74 FR 30273 (June 25, 2009)

addressed in the most complete manner possible.

For the reasons identified above, we are postponing the preliminary determination under section 733(c)(1)(B) of the Act, by 50 days to no later than December 28, 2009. The deadline for the final determination will continue to be 75 days after the date of the preliminary determination, unless extended.

This notice is issued and published pursuant to sections 733(c)(2), 733(f) and 777(i) of the Act.

Dated: October 16, 2009.

Ronald K. Lorentzen,

Acting Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. E9-25444 Filed 10-21-09; 8:45 am]

BILLING CODE 3510-DS-S

DEPARTMENT OF COMMERCE

International Trade Administration

[A-533-848]

Notice of Final Determination of Sales at Less Than Fair Value: Commodity Matchbooks from India

AGENCY: Import Administration, International Trade Administration, Department of Commerce

SUMMARY: We determine that imports of commodity matchbooks are being, or are likely to be, sold in the United States at less than fair value (LTFV), as provided in section 735 of the Tariff Act of 1930, as amended (the Act). The estimated margins of sales at LTFV are shown in the "Final Determination" section of this notice.

EFFECTIVE DATE: October 22, 2009.

FOR FURTHER INFORMATION CONTACT: Holly Phelps or Elizabeth Eastwood, AD/CVD Operations, Office 2, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230; telephone: (202) 482-0656 and (202) 482-3874, respectively.

SUPPLEMENTARY INFORMATION:

Background

On June 2, 2009, the Department published in the **Federal Register** the preliminary determination of sales at LTFV in the antidumping duty investigation of commodity matchbooks from India. *See Commodity Matchbooks from India: Notice of Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination*, 74 FR 26366 (June 2, 2009) (*Preliminary Determination*).

In June 2009, we verified the questionnaire responses of the sole respondent in this case, Triveni Safety Matches Pvt. Ltd. (Triveni), in accordance with section 782(i) of the Act. Although we provided interested parties an opportunity to comment on the *Preliminary Determination* and the Department's verification findings, no interested party submitted a case brief.

Period of Investigation

The period of investigation is October 1, 2007, through September 30, 2008. This period corresponds to the four most recent fiscal quarters prior to the month of the filing of the petition.

Scope of Investigation

The scope of this investigation covers commodity matchbooks, also known as commodity book matches, paper matches or booklet matches.¹ Commodity matchbooks typically, but do not necessarily, consist of twenty match stems which are usually made from paperboard or similar material tipped with a match head composed of any chemical formula. The match stems may be stitched, stapled, or otherwise fastened into a matchbook cover of any material, on which a striking strip composed of any chemical formula has been applied to assist in the ignition process.

Commodity matchbooks included in the scope of this investigation may or may not contain printing. For example, they may have no printing other than the identification of the manufacturer or importer. Commodity matchbooks may also be printed with a generic message such as "Thank You" or a generic image such as the American Flag, with store brands (*e.g.*, Kroger, 7-Eleven, Shurfine or Giant); product brands for national or regional advertisers such as cigarettes or alcoholic beverages; or with corporate brands for national or regional distributors (*e.g.*, Penley Corp. or Diamond Brands). They all enter retail distribution channels. Regardless of the materials used for the stems of the matches and regardless of the way the match stems are fastened to the matchbook cover, all commodity matchbooks are included in the scope of this investigation.

All matchbooks, including commodity matchbooks, typically comply with the United States Consumer Product Safety Commission

¹ Such commodity matchbooks are also referred to as "for resale" because they always enter into retail channels, meaning businesses that sell a general variety of tangible merchandise, *e.g.*, convenience stores, supermarkets, dollar stores, drug stores and mass merchandisers.

(CPSC) Safety Standard for Matchbooks, codified at 16 CFR § 1202.1 *et seq.*

The scope of this investigation excludes promotional matchbooks, often referred to as "not for resale," or "specialty advertising" matchbooks, as they do not enter into retail channels and are sold to businesses that provide hospitality, dining, drinking or entertainment services to their customers, and are given away by these businesses as promotional items. Such promotional matchbooks are distinguished by the physical characteristic of having the name and/or logo of a bar, restaurant, resort, hotel, club, café/coffee shop, grill, pub, eatery, lounge, casino, barbecue or individual establishment printed prominently on the matchbook cover. Promotional matchbook cover printing also typically includes the address and the phone number of the business or establishment being promoted.² Also excluded are all other matches that are not fastened into a matchbook cover such as wooden matches, stick matches, box matches, kitchen matches, pocket matches, penny matches, household matches, strike-anywhere matches (aka "SAW" matches), strike-on-box matches (aka "SOB" matches), fireplace matches, barbecue/grill matches, fire starters, and wax matches.

The merchandise subject to this investigation is properly classified under subheading 3605.00.0060 of the Harmonized Tariff Schedule of the United States (HTSUS). Subject merchandise may also enter under subheading 3605.00.0030 of the HTSUS. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise under investigation is dispositive.

Changes Since the Preliminary Determination

Based on our findings at verification, we have made certain changes to the margin calculations for Triveni. For a discussion of these changes, see the October 15, 2009, memorandum from Holly Phelps, Analyst, to the File, entitled, "Calculations Performed for Triveni Safety Matches Pvt. Ltd. for the Final Determination in the 2007-2008

² The gross distinctions between commodity matchbooks and promotional matchbooks may be summarized as follows: (1) if it has no printing, or is printed with a generic message such as "Thank You" or a generic image such as the American Flag, or printed with national or regional store brands or corporate brands, it is commodity; (2) if it has printing, and the printing includes the name of a bar, restaurant, resort, hotel, club, café/coffee shop, grill, pub, eatery, lounge, casino, barbecue, or individual establishment prominently displayed on the matchbook cover, it is promotional.

Antidumping Duty Investigation of Commodity Matchbooks from India.” See also the October 15, 2009, memorandum from LaVonne Clark, Senior Accountant, to Neal Halper, Director, Office of Accounting, entitled, “Constructed Value Calculation Adjustments for the Final Determination - Triveni Safety Matches Pvt. Ltd.”

Verification

As provided in section 782(i) of the Act, we verified the sales and cost information submitted by Triveni for use in our final determination. We used standard verification procedures including an examination of relevant accounting and production records, and original source documents provided by Triveni. Our sales and cost verification results are outlined in separate verification reports. See the June 24, 2009, memorandum from Holly Phelps, Analyst, to James P. Maeder, Director, Office 2, entitled, “Verification of the Sales Response of Triveni Safety Matches Pvt. Ltd. (Triveni) in the Less-Than-Fair-Value Investigation on Commodity Matchbooks from India.” See also the July 16, 2009, memorandum from LaVonne Clark, Senior Accountant, to Neal Halper, Director, Office of Accounting, entitled, “Verification of the Cost Response of Triveni Safety Matches Pvt., Ltd. in the Antidumping Duty Investigation of Commodity Matchbooks from India.”

Continuation of Suspension of Liquidation

Pursuant to 735(c)(1)(B) of the Act, we will instruct U.S. Customs and Border Protection (CBP) to continue to suspend liquidation of all entries of subject merchandise from India, entered, or withdrawn from warehouse, for consumption on or after June 2, 2009, the date of publication of the preliminary determination in the **Federal Register**. CBP shall require a cash deposit or the posting of a bond equal to the estimated amount by which the normal value exceeds the U.S. price as shown below, adjusted for export subsidies found in the final determination of the companion countervailing duty investigation of this merchandise. Specifically, consistent with our practice, where the product under investigation is also subject to a concurrent countervailing duty investigation, we instruct CBP to require a cash deposit or posting of a bond equal to the amount by which the normal value exceeds the export price or constructed export price, as indicated below, less the amount of the countervailing duty determined to constitute an export subsidy. See, e.g.,

Notice of Final Determination of Sales at Less Than Fair Value: Carbazole Violet Pigment 23 From India, 69 FR 67306, 67307 (Nov. 17, 2004).

Accordingly, for cash deposit purposes, we are subtracting from the applicable cash deposit rate that portion of the rate attributable to the export subsidies found in the affirmative countervailing duty determination for each respondent (*i.e.*, 9.88 percent for Triveni, and 9.88 percent for “All Others”). After the adjustment for the cash deposit rates attributed to export subsidies, the resulting cash deposit rates will be 56.19 percent for Triveni and 56.19 percent for “All Others.” These instructions suspending liquidation will remain in effect until further notice.

Final Determination Margins

The weighted-average dumping margins are as follows:

Producer/Exporter	Weighted-Average Margin (percent)
Triveni Safety Matches Pvt. Ltd.	66.07
All Others	66.07

“All Others” Rate

Section 735(c)(5)(A) of the Act provides that the estimated “All Others” rate shall be an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero or *de minimis* margins, and any margins determined entirely under section 776 of the Act. Triveni is the only respondent in this investigation. Therefore, for purposes of determining the “All Others” rate and pursuant to section 735(c)(5)(A) of the Act, we are using the weighted-average dumping margin calculated for Triveni, as referenced above. See, e.g., *Notice of Final Determination of Sales at Less Than Fair Value: Stainless Steel Sheet and Strip in Coils From Italy*, 64 FR 30750, 30755 (June 8, 1999); and *Coated Free Sheet Paper from Indonesia: Notice of Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination*, 72 FR 30753, 30757 (June 4, 2007), unchanged in *Notice of Final Determination of Sales at Less Than Fair Value: Coated Free Sheet Paper from Indonesia*, 72 FR 60636 (Oct. 25, 2007).

Disclosure

We will disclose the calculations performed within five days of the date of publication of this notice to parties in this proceeding in accordance with 19 CFR 351.224(b).

ITC Notification

In accordance with section 735(d) of the Act, we have notified the International Trade Commission (ITC) of our final determination. As our final determination is affirmative, the ITC will determine within 45 days whether imports of the subject merchandise are causing material injury, or threat of material injury, to an industry in the United States. If the ITC determines that material injury or threat of injury does not exist, the proceeding will be terminated and all securities posted will be refunded or canceled. If the ITC determines that such injury does exist, the Department will issue an antidumping duty order directing CBP to assess antidumping duties on all imports of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation.

Return or Destruction of Proprietary Information

This notice will serve as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

We are issuing and publishing this determination and notice in accordance with sections 735(d) and 777(i) of the Act.

Dated: October 15, 2009.

Ronald K. Lorentzen,

Acting Assistant Secretary for Import Administration.

[FR Doc. E9-25446 Filed 10-21-09; 8:45 am]

BILLING CODE 3510-DS-S

DEPARTMENT OF COMMERCE

International Trade Administration

[A-570-960, A-583-845]

Certain Standard Steel Fasteners From the People's Republic of China and Taiwan: Initiation of Antidumping Duty Investigations

DATES: *Effective Date:* October 22, 2009.

FOR FURTHER INFORMATION CONTACT:

Mark Flessner or Robert James, AD/CVD Operations Office 7, (202) 482-6312 or (202) 482-0649, respectively (Taiwan); Susan Pulongbarit or Jerry Huang, AD/CVD Operations Office 9, (202) 482-

4031 or (202) 482-4047, respectively (People's Republic of China); Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230.

SUPPLEMENTARY INFORMATION: On September 23, 2009, the Department of Commerce (the Department) received petitions concerning imports of certain standard steel fasteners (fasteners) from the People's Republic of China (PRC) and Taiwan filed in proper form by Nucor Fastener (Petitioner). See Petitions for the Imposition of Antidumping and Countervailing Duties: Certain Standard Steel Fasteners from the People's Republic of China and Taiwan, dated September 23, 2009 (Petition). On September 30, 2009, the Department issued additional requests for information and clarification of certain areas of the Petition. Petitioner timely filed additional information pertaining to Taiwan and the PRC on October 5, 2009. See Petition for the Imposition of Antidumping Duties on Certain Standard Steel Fasteners from Taiwan: Response to Deficiency Questionnaire, dated October 5, 2009 (Taiwan Deficiency Response); see also Petition for the Imposition of Antidumping Duties on Certain Standard Steel Fasteners from the People's Republic of China: Response to Deficiency Questionnaire, dated October 5, 2009 (PRC Deficiency Response). Petitioner further timely filed additional information pertaining to general issues in the Petition on October 6, 2009 (see Petitions for the Imposition of Antidumping and Countervailing Duties on Certain Standard Steel Fasteners from the People's Republic of China and Taiwan: Response to General Issues Deficiency Questionnaire, dated October 6, 2009 (Supplement to the AD/CVD Petitions)), on October 8, 2009 (see Petitions for the Imposition of Antidumping and Countervailing Duties on Certain Standard Steel Fasteners from the People's Republic of China and Antidumping Duties on Certain Standard Steel Fasteners from Taiwan: Submission of Additional Information Related to The Calculation of Industry Standing, dated October 8, 2009 (Industry Support Supplement)), also on October 8, 2009, (see Petitions for the Imposition of Antidumping and Countervailing Duties on Certain Standard Steel Fasteners from the People's Republic of China and Taiwan: Response to General Issues Deficiency Questionnaire, dated October 8, 2009 (Second Supplement to the AD/CVD Petitions)), also on October 8, 2009, (see Petitions for the Imposition of

Antidumping and Countervailing Duties on Certain Standard Steel Fasteners from the People's Republic of China and Antidumping Duties on Certain Standard Steel Fasteners from Taiwan: Confirmation of Simultaneous Filing at DOC and ITC, dated October 8, 2009 (Simultaneous Filing Supplement)), on October 9, 2009 (see Petitions for the Imposition of Antidumping and Countervailing Duties on Certain Standard Steel Fasteners from the People's Republic of China and Antidumping Duties on Certain Standard Steel Fasteners from Taiwan: Revised Description of Scope and Uses and Technical Characteristics/U.S. Producers List, dated October 9, 2009 (Third Supplement to the AD/CVD Petitions)), and on October 13, 2009 (see Certain Standard Steel Fasteners from the People's Republic of China and Certain Standard Steel Fasteners from Taiwan).

The period of investigation (POI) for the PRC is January 1, 2009, through June 30, 2009. The POI for Taiwan is July 1, 2008, through June 30, 2009. See 19 CFR 351.204(b)(1).

In accordance with section 732(b) of the Tariff Act of 1930, as amended (the Tariff Act), Petitioner alleges that imports of certain standard steel fasteners from the PRC and Taiwan are being, or are likely to be, sold in the United States at less than fair value, within the meaning of section 731 of the Tariff Act, and that such imports are materially injuring, or threatening material injury to, an industry in the United States.

The Department finds Petitioner filed the Petition on behalf of the domestic industry because Petitioner is an interested party, as defined in section 771(9)(C) of the Tariff Act, and has demonstrated sufficient industry support with respect to the antidumping duty investigations that Petitioner is requesting the Department to initiate (see "Determination of Industry Support for the Petitions" section below).

Scope of the Investigations

The products covered by these investigations are fasteners from the PRC and Taiwan. For a full description of the scope of the investigations, please see "Scope of Investigations," in Appendix I of this notice. The Department, after consulting with Petitioner, made minor changes to the scope language submitted by Petitioner in the Third Supplement to the AD/CVD Petitions. See Memorandum to the file from Steve Bezirgianian, Analyst, entitled "Certain Standard Steel Fasteners from the People's Republic of China (A-570-960 and C-570-961) and

Taiwan (A-583-845): Revisions to Petitioner's Proposed October 9, 2009, Scope Language," dated October 13, 2009.

Comments on Scope of Investigations

During our review of the Petition, we discussed the scope with Petitioner to ensure that it is an accurate reflection of the products for which the domestic industry is seeking relief. Moreover, as discussed in the preamble to the regulations (*Antidumping Duties; Countervailing Duties; Final Rule*, 62 FR 27296, 27323 (May 19, 1997)), we are setting aside a period for interested parties to raise issues regarding product coverage. The Department encourages all interested parties to submit such comments by Monday, November 2, 2009, which is twenty calendar days from the signature date of this notice. Comments should be addressed to Import Administration's APO/Dockets Unit, Room 1870, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230. The period of scope consultations is intended to provide the Department with ample opportunity to consider all comments and to consult with parties prior to the issuance of the preliminary determinations.

Comments on Product Characteristics for Antidumping Duty Questionnaires

We are requesting comments from interested parties regarding the appropriate physical characteristics of fasteners to be reported in response to the Department's antidumping questionnaires. This information will be used to identify the key physical characteristics of the merchandise under consideration in order to more accurately report the relevant factors and costs of production, as well as to develop appropriate product comparison criteria.

Interested parties may provide information or comments that they believe are relevant to the development of an accurate listing of physical characteristics. Specifically, they may provide comments as to which characteristics are appropriate to use as: (1) General product characteristics; and (2) the product comparison criteria. We note that it is not always appropriate to use all product characteristics as product comparison criteria. We base product comparison criteria on meaningful commercial differences among products. In other words, while there may be some physical product characteristics utilized by manufacturers to describe fasteners, it may be that only a select few product characteristics take into account

commercially meaningful physical characteristics. In addition, interested parties may comment on the order in which the physical characteristics should be used in product matching. Generally, the Department attempts to list the most important physical characteristics first and the least important characteristics last.

In order to consider the suggestions of interested parties in developing and issuing the antidumping duty questionnaires, we must receive comments at the above-referenced address by October 27, 2009. Additionally, rebuttal comments must be received by November 3, 2009.

Determination of Industry Support for the Petitions

Section 732(b)(1) of the Tariff Act requires that a petition be filed on behalf of the domestic industry. Section 732(c)(4)(A) of the Tariff Act provides that a petition meets this requirement if the domestic producers or workers who support the petition account for: (i) At least 25 percent of the total production of the domestic like product; and (ii) more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the petition. Moreover, section 732(c)(4)(D) of the Tariff Act provides that, if the petition does not establish support of domestic producers or workers accounting for more than 50 percent of the total production of the domestic like product, the Department shall: (i) Poll the industry or rely on other information in order to determine if there is support for the petition, as required by subparagraph (A); or (ii) determine industry support using a statistically valid sampling method to poll the industry.

Section 771(4)(A) of the Tariff Act defines the "industry" as the producers as a whole of a domestic like product. Thus, to determine whether a petition has the requisite industry support, the statute directs the Department to look to producers and workers who produce the domestic like product. The International Trade Commission (the Commission), which is responsible for determining whether "the domestic industry" has been injured, must also determine what constitutes a domestic like product in order to define the industry. While both the Department and the Commission must apply the same statutory definition regarding the domestic like product (see section 771(10) of the Tariff Act), they do so for different purposes and pursuant to a separate and distinct authority. In addition, the Department's determination is subject to limitations of

time and information. Although this may result in different definitions of the like product, such differences do not render the decision of either agency contrary to law. See *USEC, Inc. v. United States*, 132 F. Supp. 2d 1, 8 (Ct. Int'l Trade 2001), citing *Algoma Steel Corp., Ltd. v. United States*, 688 F. Supp. 639, 644 (Ct. Int'l Trade 1988), *aff'd* 865 F.2d 240 (Fed. Cir. 1989), *cert. denied* 492 U.S. 919 (1989).

Section 771(10) of the Tariff Act defines the domestic like product as "a product which is like, or in the absence of like, most similar in characteristics and uses with, the article subject to an investigation under this title." Thus, the reference point from which the domestic like product analysis begins is "the article subject to an investigation" (i.e., the class or kind of merchandise to be investigated, which normally will be the scope as defined in the petition).

With regard to the domestic like product, Petitioner does not offer a definition of domestic like product distinct from the scope of the investigations. Based on our analysis of the information submitted on the record, we have determined that fasteners constitute a single domestic like product and we have analyzed industry support in terms of that domestic like product. For a discussion of the domestic like product analysis in this case, see Antidumping Duty Investigation Initiation Checklist: Certain Standard Steel Fasteners from the People's Republic of China (PRC Checklist), at Attachment II, Industry Support, and Antidumping Duty Investigation Initiation Checklist: Certain Standard Steel Fasteners from Taiwan (Taiwan Checklist), at Attachment II, Industry Support, on file in the Central Records Unit (CRU), Room 1117 of the main Department of Commerce building.

In determining whether Petitioner has standing under section 732(c)(4)(A) of the Tariff Act, we considered the industry support data contained in the Petitions with reference to the domestic like product as defined in the "Scope of Investigations" section above. To establish industry support, Petitioner provided its production of the domestic like product for the year 2008, and compared this to the estimated total production of the domestic like product for the entire domestic industry. See Volume I of the Petition, at 2–3, Exhibit I–10; see also Supplement to the AD/CVD Petitions, at 17–18, Exhibit I–Supp-6, and Industry Support Supplement, at Attachment 1. To estimate 2008 production of the domestic like product, Petitioner used its own data and industry specific

knowledge. See Industry Support Supplement, at Attachment I; see also PRC Checklist at Attachment II, Taiwan Checklist at Attachment II. Petitioner calculated total domestic production based on its own production plus estimates regarding the other producers of the domestic like product in the United States. *Id.* We have relied upon data Petitioner provided for purposes of measuring industry support. For further discussion, see Initiation Checklist at Attachment II.

Our review of the data provided in the Petitions, supplemental submissions, and other information readily available to the Department indicates that Petitioner has established industry support. First, the Petitions established support from domestic producers (or workers) accounting for more than 50 percent of the total production of the domestic like product and, as such, the Department is not required to take further action in order to evaluate industry support (e.g., polling). See section 732(c)(4)(D) of the Tariff Act; see also PRC Checklist at Attachment II, and Taiwan Checklist at Attachment II. Second, the domestic producers (or workers) have met the statutory criteria for industry support under section 732(c)(4)(A)(i) of the Tariff Act because the domestic producers (or workers) who support the Petitions account for at least 25 percent of the total production of the domestic like product. See PRC Checklist at Attachment II, and Taiwan Checklist at Attachment II. Finally, the domestic producers (or workers) have met the statutory criteria for industry support under section 732(c)(4)(A)(ii) of the Tariff Act because the domestic producers (or workers) who support the Petitions account for more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the Petitions. Accordingly, the Department determines that the Petitions were filed on behalf of the domestic industry within the meaning of section 732(b)(1) of the Tariff Act. *Id.*

The Department finds that Petitioner filed the Petitions on behalf of the domestic industry because it is an interested party as defined in section 771(9)(C) of the Tariff Act and it has demonstrated sufficient industry support with respect to the antidumping duty investigations that it is requesting the Department initiate. *Id.*

Allegations and Evidence of Material Injury and Causation

Petitioner alleges that the U.S. industry producing the domestic like product is being materially injured, or is

threatened with material injury, by reason of the imports of the subject merchandise sold at less than normal value (NV). In addition, Petitioner alleges that subject imports exceed the negligibility threshold provided for under section 771(24)(A) of the Tariff Act.

Petitioner contends that the industry's injured condition is illustrated by reduced market share, underselling and price depressing and suppressing effects, increased import penetration, declining sales, reduced production, reduced capacity, increased raw material cost, abandoned product lines, reduced shipments, reduced wages and hours worked, and an overall decline in financial performance. We have assessed the allegations and supporting evidence regarding material injury, threat of material injury, and causation, and we have determined that these allegations are properly supported by adequate evidence and meet the statutory requirements for initiation. *See* PRC Checklist at Attachment III, Injury, and Taiwan Checklist at Attachment III, Injury.

Allegations of Sales at Less Than Fair Value

The following is a description of the allegations of sales at less than fair value upon which the Department based its decision to initiate these investigations of imports of fasteners from the PRC and Taiwan. The sources of data for the deductions and adjustments relating to the U.S. price, the factors of production (for the PRC), and price-based NV (for Taiwan) are also discussed in the country-specific initiation checklists. *See* PRC Checklist and Taiwan Checklist.

U.S. Price

The PRC

For the PRC, Petitioner calculated export price (EP) based on documentation of offers for sale obtained from a confidential source. *See* PRC Initiation Checklist; *see also* Petition Vol. II at 3 and Exhibit II-2. Based on the terms of sale, Petitioner adjusted the export price for brokerage and handling, ocean freight, insurance and port expenses, as well as U.S. inland freight expenses. *See* PRC Initiation Checklist; *see also* Petition Vol. II at 5-13 and Exhibit II-5.

Taiwan

For Taiwan, Petitioner based U.S. price on EP because, it maintains, Taiwanese producers typically sell the subject merchandise either directly to unaffiliated U.S. customers or via an unaffiliated trading company to the U.S.

customer. Petitioner obtained POI prices of fasteners produced by the Taiwanese manufacturer Jinn Her Enterprise Co., Ltd. (Jinn Her). Petitioner substantiated the U.S. prices used with affidavits from persons who obtained the information. Petitioner deducted, where appropriate, movement expenses (foreign inland freight, foreign port, brokerage and handling charges, ocean freight, and U.S. inland freight). Petitioners also deducted an amount for imputed credit expenses, based upon the presumed terms of payment. *See* Taiwan Checklist; *see also* Petition Vol. IV at 2-8 and Exhibits IV-1 to IV-15, and Taiwan Deficiency Response at Exhibits IV-Supp-1 to IV-Supp-5.

Normal Value

The PRC

Petitioner claims the PRC is a non-market economy (NME) country and that no determination to the contrary has been made by the Department. *See* Petition Vol. II at 14. In accordance with section 771(18)(C)(i) of the Act, the presumption of NME status remains in effect until revoked by the Department. The presumption of NME status for the PRC has not been revoked by the Department and, therefore, remains in effect for purposes of the initiation of this investigation. Accordingly, the NV of the product for the PRC investigation is appropriately based on factors of production valued in a surrogate market-economy country in accordance with section 773(c) of the Act. In the course of the PRC investigation, all parties, including the public, will have the opportunity to provide relevant information related to the issue of the PRC's NME status and the granting of separate rates to individual exporters.

Petitioner contends that India is the appropriate surrogate country for the PRC because: (1) it is at a level of economic development comparable to that of the PRC and (2) it is a significant producer and exporter of comparable merchandise. *See* Petition Vol. II at 14-16. Based on the information provided by Petitioner, we believe that it is appropriate to use India as a surrogate country for initiation purposes. After initiation of the investigation, interested parties will have the opportunity to submit comments regarding surrogate country selection and, pursuant to 19 CFR 351.301(c)(3)(i), will be provided an opportunity to submit publicly available information to value factors of production within 40 days after the date of publication of the preliminary determination.

Petitioner calculated the NV and dumping margins using the

Department's NME methodology as required by 19 CFR 351.202(b)(7)(i)(C) and 19 CFR 351.408. Petitioner calculated NV based on consumption rates of the factors of production on the average consumption rates of a fasteners producer in the United States (Surrogate Domestic Producer) for identical or similar merchandise. *See* Petition Vol. II at 2 and 16-17 and Exhibit II-16. In calculating NV, Petitioner based the quantity of each of the inputs used to manufacture and pack fasteners in the PRC on product-specific production costs and/or consumption rates of the Surrogate Domestic Producer during the POI. *See* Petition Vol. II at 16-17 and Exhibit II-16. Petitioner states that the actual usage rates of the foreign manufacturers of fasteners, Autocraft Industrial (Autocraft) and Shanghai Prime Machinery Co., Ltd. (Shanghai Prime), are not reasonably available; however, Petitioner notes that according to the information available to Petitioner, the production of fasteners by Autocraft and Shanghai Prime relies on similar production methods to the Surrogate Domestic Producer. *See* Petition Vol. II at 16 and 19 and 16-17 and Exhibit II-16.

Petitioner determined the consumption quantities of all raw materials and packing materials based on the production experience of the Surrogate Domestic Producer. *See* Petition Vol. II at 2 and 19-20. Petitioner valued the factors of production based on reasonably available, public surrogate country data, specifically, Indian import statistics from the Global Trade Atlas (GTA). *See* the PRC Deficiency Response at 1 and Exhibits II-Supp-1 and 2. Petitioner excluded from these import statistics imports from countries previously determined by the Department to be NME countries. Petitioner also excluded import statistics from Indonesia, the Republic of Korea, and Thailand, as the Department has previously excluded prices from these countries because they maintain broadly available, non-industry-specific export subsidies. *Id.*, at 1 and Exhibits II-Supp-1 and 2. In addition, the Petitioner made currency conversions, where necessary, based on the POI-average rupee/U.S. dollar exchange rate, as reported on the Department's Web site. *See* Petition Vol. II at 21 and Exhibit II-8. Petitioner determined labor costs using the labor consumption, in hours, derived from the Surrogate Domestic Producer's experience. *See* Exhibit II-16 and PRC Deficiency Response at Exhibit II-Supp-2. Petitioner valued labor costs using the Department's NME Wage Rate for the

PRC at <http://ia.ita.doc.gov/wages/05wages/05wages-051608.html>. See Petition Vol. II at 26. For purposes of initiation, the Department determines that the surrogate values used by Petitioner are reasonably available and, thus, acceptable for purposes of initiation.

Petitioner determined electricity costs using the electricity consumption, in kilowatt hours, derived from the Surrogate Domestic Producer's experience. See Petition Vol. II at 26 and Exhibit II-16. Petitioner valued electricity using the Indian electricity rate reported by the Central Electric Authority of the Government of India. See PRC Deficiency Response at 3 and Exhibits II-Supp-2 and II-Supp-5.

Petitioner determined natural gas costs using the natural gas consumption derived from the Surrogate Domestic Producer's experience. See Volume II of the Petition at Exhibit II-16. Petitioner valued natural gas using the CRISIL natural gas rate that the Department replied upon in several recent investigations. See, e.g., *Initiation of Antidumping Duty Investigations: Light-Walled Rectangular Pipe and Tube from Republic of Korea, Mexico, Turkey, and the People's Republic of China*, 72 FR 40274 (July 24, 2007). Petitioner converted the amounts denominated in Indian rupees to USD using the Department's published exchange rates for the time period for the prospective POI. See Volume II of the Petition at 25-26 and Exhibit II-22.

Petitioner determined nitrogen costs using a price quote from Bhoruka Gases Ltd, which was previously relied upon in *Frontseating Valves from the People's Republic of China: Final Determination of Sales at Less Than Fair Value and Final Negative Determination of Critical Circumstances*, 74 FR 10886 (March 13, 2009) and Petition Vol. II at 25 and Exhibit II-20, and the Supplement to the Petition Vol. II at 2.

Petitioner determined the consumption of all packing materials based on the Surrogate Domestic Producer's experience. See Volume II of the Petition at 28 and Exhibit II-16. Petitioner valued packing materials based on Indian import statistics from GTA, and as noted above, excluded NME countries as well as countries with general export subsidies. See the Supplement to the AD PRC Petition at Exhibit II-Supp-1. In addition, Petitioner made currency conversions, where necessary, based on the POI-average rupee/USD exchange rate, as reported on the Department's Web site. See the Supplement to the AD PRC Petition at Exhibit II-Supp-3.

Petitioner based factory overhead, selling, general and administrative (SG&A), and profit on data from Sundaram Fasteners Ltd. (SFL), a producer of similar merchandise, for the 2007-2008 fiscal year. See Petition Vol. II at 27-28 and Exhibit II-24. For purposes of the initiation, the Department finds Petitioner's use of SFL's unconsolidated financial ratios appropriate.

Taiwan

Petitioner based NV on price quotes for fasteners offered for sale in Taiwan by Jinn Her. These price and adjustment data were obtained through market research commissioned by petitioner. The price and adjustment data involve merchandise that is both commonly sold in the home market, and is substantially identical to the merchandise sold in the United States. Since the prices quoted were on an "ex-works" basis, Petitioner made no adjustments for movement expenses. Petitioner adjusted NV for imputed credit expenses. For comparison to EP, petitioner then added U.S. credit expenses. See Taiwan Checklist.

Fair-Value Comparisons

Based on the data provided by Petitioner, there is reason to believe that imports of fasteners from the PRC and Taiwan are being, or are likely to be, sold in the United States at less than fair value. Based on a comparison of U.S. prices and NV calculated in accordance with section 773(c) of the Tariff Act, the estimated dumping margins for fasteners from the PRC range from 66.87 percent to 205.97 percent. See PRC Checklist and PRC Deficiency Response at Exhibit II-Supp-4. Based on a comparison of U.S. price and NV, the estimated dumping margins for fasteners from Taiwan range from 51.39 percent to 114.14 percent. See Taiwan Checklist; see also Petition Vol. IV at 18-19 and Exhibit IV-20, and Taiwan Deficiency Response at 11 and Exhibit IV-Supp-8.

Initiation of Antidumping Investigations

Based upon the examination of the Petition on fasteners from the PRC and Taiwan, the Department finds the Petition meets the requirements of section 732 of the Tariff Act. Therefore, we are initiating antidumping duty investigations to determine whether imports of fasteners from the PRC and Taiwan are being, or are likely to be, sold in the United States at less than fair value. In accordance with section 733(b)(1)(A) of the Tariff Act and 19 CFR 351.205(b)(1), unless postponed,

we will make our preliminary determinations no later than 140 days after the date of this initiation.

Targeted-Dumping Allegations

On December 10, 2008, the Department issued an interim final rule for the purpose of withdrawing 19 CFR 351.414(f) and (g), the regulatory provisions governing the targeted-dumping analysis in antidumping duty investigations, and the corresponding regulation governing the deadline for targeted-dumping allegations, 19 CFR 351.301(d)(5). See *Withdrawal of the Regulatory Provisions Governing Targeted Dumping in Antidumping Duty Investigations*, 73 FR 74930 (December 10, 2008). The Department stated that "withdrawal will allow the Department to exercise the discretion intended by the statute and, thereby, develop a practice that will allow interested parties to pursue all statutory avenues of relief in this area." *Id.*, 73 FR at 74931.

In order to accomplish this objective, if any interested party wishes to make a targeted-dumping allegation in either of these investigations pursuant to section 777A(d)(1)(B) of the Tariff Act, such allegations are due no later than 45 days before the scheduled date of the country-specific preliminary determination.

Respondent Selection

The PRC

For this investigation, the Department will request quantity and value information from all known exporters and producers identified with complete contact information in the Petition. The quantity and value data received from NME exporters/producers will be used as the basis to select the mandatory respondents.

The Department requires that the respondents submit a response to both the quantity and value questionnaire and the separate-rate application by the respective deadlines in order to receive consideration for separate-rate status. See *Circular Welded Austenitic Stainless Pressure Pipe from the People's Republic of China: Initiation of Antidumping Duty Investigation*, 73 FR 10221, 10225 (February 26, 2008); *Initiation of Antidumping Duty Investigation: Certain Artist Canvas From the People's Republic of China*, 70 FR 21996, 21999 (April 28, 2005). The Department will post the quantity and value questionnaire along with the filing instructions on the Import Administration Web site at <http://ia.ita.doc.gov/ia-highlights-and-news.html>, and a response to the

quantity and value questionnaire is due no later than November 3, 2009. Also, the Department will send the quantity and value questionnaire to those PRC companies identified in the Petition at Exhibit I-4 and in the General Issues Deficiency Response at Exhibit I-Supp-1.

Taiwan

For this investigation, the Department intends to select respondents based on U.S. Customs and Border Protection (CBP) data for U.S. imports under the Harmonized Tariff Schedule of the United States (HTSUS) numbers 7318.15.2030, 7318.15.2055, 7318.15.2065, 7318.15.8065, 7318.15.8085, and 7318.16.0085, the six HTSUS categories most specific to the subject merchandise, during the POI. We intend to release the CBP data under Administrative Protective Order (APO) to all parties with access to information protected by APO within five days of publication of this **Federal Register** notice. We note that Petitioner has stated that five of the six HTS categories covering subject merchandise "are broad basket categories that also cover products outside the scope of this investigation." See Petition at 9 and Exhibit I-5. Accordingly, the Department invites additional comments regarding the CBP data and respondent selection, including the propriety of basing respondent selection upon CBP data in this investigation, within ten days of publication of this **Federal Register** notice.

Interested parties must submit applications for disclosure under APO in accordance with 19 CFR 351.305. Instructions for filing such applications may be found on the Department's Web site at <http://ia.ita.doc.gov/apo>.

Separate Rates Application

In order to obtain separate-rate status in NME investigations, exporters and producers must submit a separate-rate status application. See Policy Bulletin 05.1: Separate-Rates Practice and Application of Combination Rates in Antidumping Investigations involving Non-Market Economy Countries, dated April 5, 2005 (Separate Rates and Combination Rates Bulletin), available on the Department's Web site at <http://ia.ita.doc.gov/policy/bull05-1.pdf>. Based on our experience in processing the separate-rate applications in previous antidumping duty investigations, we have modified the application for this investigation to make it more administrable and easier for applicants to complete. See, e.g., *Initiation of Antidumping Duty Investigation: Certain New Pneumatic Off-the-Road*

Tires From the People's Republic of China, 72 FR 43591, 43594-95 (August 6, 2007). The specific requirements for submitting the separate-rate application in this investigation are outlined in detail in the application itself, which will be available on the Department's Web site at <http://ia.ita.doc.gov/ia-highlights-and-news.html> on the date of publication of this initiation notice in the **Federal Register**. The separate-rate application will be due 60 days after publication of this initiation notice. For exporters and producers who submit a separate-rate status application and subsequently are selected as mandatory respondents, these exporters and producers will no longer be eligible for consideration for separate rate status unless they respond to all parts of the questionnaire as mandatory respondents. As noted in the "Respondent Selection" section above, the Department requires that respondents submit a response to both the quantity and value questionnaire and the separate rate application by the respective deadlines in order to receive consideration for separate-rate status. The quantity and value questionnaire will be available on the Department's Web site at <http://ia.ita.doc.gov/ia-highlights-and-news.html> on the date of the publication of this initiation notice in the **Federal Register**.

Use of Combination Rates in an NME Investigation

The Department will calculate combination rates for certain respondents that are eligible for a separate rate in this investigation. The Separate Rates and Combination Rates Bulletin states:

[W]hile continuing the practice of assigning separate rates only to exporters, all separate rates that the Department will now assign in its NME investigations will be specific to those producers that supplied the exporter during the period of investigation. Note, however, that one rate is calculated for the exporter and all of the producers which supplied subject merchandise to it during the period of investigation. This practice applies both to mandatory respondents receiving an individually calculated separate rate as well as the pool of non-investigated firms receiving the weighted-average of the individually calculated rates. This practice is referred to as the application of "combination rates" because such rates apply to specific combinations of exporters and one or more producers. The cash-deposit rate assigned to an exporter will apply only to merchandise both exported by the firm in question and produced by a firm that supplied the exporter during the period of investigation.

See Separate Rates and Combination Rates Bulletin at 6 (emphasis added).

Distribution of Copies of the Petition

In accordance with section 732(b)(3)(A) of the Tariff Act and 19 CFR 351.202(f), copies of the public versions of the Petition have been provided to the representatives of the Governments of the PRC and Taiwan. Because of the large number of producers/exporters identified in the Petition, the Department considers the service of the public version of the Petition to the foreign producers/exporters satisfied by the delivery of the public version to the Government of the PRC and the Government of Taiwan, consistent with 19 CFR 351.203(c)(2).

Commission Notification

We have notified the Commission of our initiations, as required by section 732(d) of the Tariff Act.

Preliminary Determinations by the Commission

The Commission will preliminarily determine, no later than November 7, 2009, whether there is a reasonable indication that imports of fasteners from the PRC and Taiwan are materially injuring, or threatening material injury to a U.S. industry. A negative ITC determination with respect to any country will result in the investigation being terminated for that country; otherwise, these investigations will proceed according to statutory and regulatory time limits.

This notice is issued and published pursuant to section 777(i) of the Tariff Act.

Dated: October 13, 2009.

Ronald K. Lorentzen,
Acting Assistant Secretary for Import Administration.

Appendix I

Scope of the Investigations

The merchandise covered by the investigations consists of certain standard nuts, standard bolts, and standard cap screws, of steel other than stainless steel. Standard nuts, standard bolts, and standard cap screws covered by the investigations may have a variety of finishes, including but not limited to coating in paint, phosphates, and zinc. Standard bolts and standard cap screws covered by the investigations have a shank or thread with an actual and/or nominal diameter between 6 millimeters and 32 millimeters (inclusive). Standard bolts and standard cap screws covered by the investigations also possess a circular or hexagonal head, the surface of which may be flat or rounded (also known as "dome-shaped" or "button-headed"). Standard bolts covered by the investigations may have an attached washer face or the equivalent (e.g., a flanged head or chamfered corners on the underside of a fastener with a hexagonal-shaped head). Standard cap screws covered

by the investigations have a permanently-attached washer face. Standard nuts are covered by the investigations if they are suitable for attachment to bolts and/or cap screws covered by the investigations.

Standard bolts, standard cap screws, and standard nuts are covered by the investigations whether imported alone, attached to other subject and/or non-subject merchandise (e.g., tension control assemblies), or unattached and in combination with other subject merchandise and/or non-subject merchandise.

Standard nuts, standard bolts, and standard cap screws meet the requirements of one or more nationally recognized consensus industry standard specifications (including but not limited to those referenced below). Subject merchandise is typically certified to the specifications published by one or more consensus standards organizations such as the following: the American Society for Testing and Materials (ASTM), the Society of Automotive Engineers (SAE), the International Organization for Standardization (ISO), and the Industrial Fasteners Institute. Common specifications to which subject merchandise is certified include, but are not limited to: ASTM A194, ASTM A307, ASTM A325, ASTM A325M, ASTM A354, ASTM A449, ASTM A490, ASTM A563, ASTM F568M, ASTM F1852, ASTM F2280, SAE J429, SAE J1199, ISO 898-1, ISO 898-2, ISO 4759-1, ISO 8992, and comparable foreign and domestic specifications (including, but not limited to, metric versions of specifications such as those listed above).

Excluded from the scope of the investigations are bolts, cap screws, and nuts produced for an original equipment manufacturer (OEM) part number specific to any "automobile" as defined in 49 U.S.C. Section 32901(a)(3), any "work truck" as defined in 49 U.S.C. Section 32901(a)(19), or any "medium-duty passenger vehicle" as defined in 40 CFR Section 86.1803-01 (2009).

Also excluded from the scope of the investigations are bolts, cap screws, and nuts produced for an OEM part number specific to any "aircraft" as defined in 14 CFR Section 1.1 (2009).

Also excluded from the scope of the investigations are track bolts. Track bolts have a circular, rounded head and a shank which, immediately beneath the head, possesses an oval or elliptical shape, such that the non-round shape would restrict rotational movement of the bolt. Also excluded from the scope of the investigations are carriage bolts. Carriage bolts have a circular, rounded head and a shank which, immediately beneath the head, possesses a non-round shape (e.g., square, finned), such that the non-round shape would restrict rotational movement of the bolt. Also excluded from the scope of the investigations are socket screws. Socket screws have a head with a recessed cavity into which a shaped bit may be inserted to turn and drive the fastener.

Unless explicitly excluded from the scope of the investigations, bolts, cap screws, and nuts meeting the description of subject merchandise are covered by the investigations.

Merchandise covered by the investigations is classified in the Harmonized Tariff Schedule of the United States (HTSUS) under subheadings: 7318.15.2030, 7318.15.2055, 7318.15.2065, 7318.15.8065, 7318.15.8085, and 7318.16.0085. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise under the investigations is dispositive.

[FR Doc. E9-25194 Filed 10-21-09; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[C-570-961]

Certain Standard Steel Fasteners From the People's Republic of China: Initiation of Countervailing Duty Investigation

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

DATES: *Effective Date:* October 22, 2009.

FOR FURTHER INFORMATION CONTACT: Yasmin Nair and Joseph Shuler, AD/CVD Operations, Office 1, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482-3813 and (202) 482-1293, respectively.

SUPPLEMENTARY INFORMATION:

The Petition

On September 23, 2009, the Department of Commerce ("Department") received a countervailing duty petition concerning imports of certain standard steel fasteners ("fasteners") from the People's Republic of China ("PRC"). The petition was filed in proper form by Nucor Fastener ("Petitioner"), a domestic producer of fasteners.¹ In response to the Department's requests, Petitioner provided timely information supplementing the Petition on October 6, 7, 8, and 9, 2009.

In accordance with section 702(b)(1) of the Tariff Act of 1930, as amended ("the Act"), Petitioner alleges that manufacturers, producers, or exporters of standard steel fasteners in the PRC receive countervailable subsidies within the meaning of sections 701 and 771(5) of the Act, and that such imports are materially injuring, or threatening

material injury to, an industry in the United States.

The Department finds that Petitioner filed the Petition on behalf of the domestic industry because it is an interested party as defined in section 771(9)(C) of the Act, and Petitioner has demonstrated sufficient industry support with respect to the countervailing duty ("CVD") investigation (see "Determination of Industry Support for the Petition" section below).

Period of Investigation

The period of investigation ("POI") is January 1, 2008, through December 31, 2008.

Scope of Investigation

The products covered by the investigation are fasteners from the PRC and Taiwan. For a full description of the scope of the investigation, please see "Scope of Investigation," in Appendix I of this notice. The Department, after consulting with Petitioner, made minor changes to the scope language submitted by Petitioner in the Third Supplement to the AD/CVD Petitions, dated October 9, 2009, at Attachment 1. See Memorandum to the file from Steve Bezirgianian, Analyst, entitled "Certain Standard Steel Fasteners from the People's Republic of China (A-570-960 and C-570-961) and Taiwan (A-583-845): Revisions to Petitioner's Proposed October 9, 2009, Scope Language," dated October 13, 2009.

Comments on Scope of Investigation

During our review of the Petition, we discussed the scope with Petitioner to ensure that it is an accurate reflection of the products for which the domestic industry is seeking relief. Moreover, as discussed in the preamble to the Department's regulations (*Antidumping Duties; Countervailing Duties; Final Rule*, 62 FR 27296, 27323 (May 19, 1997)), we are setting aside a period for interested parties to raise issues regarding product coverage. The Department encourages all interested parties to submit such comments by November 2, 2009, twenty calendar days from the signature date of this notice. Comments should be addressed to Import Administration's APO/Dockets Unit, Room 1870, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230. The period for scope consultations is intended to provide the Department with ample opportunity to consider all comments and to consult with parties prior to the issuance of the preliminary determination.

¹ See Petition for the Imposition of Antidumping and Countervailing Duties Pursuant to Sections 701 and 731 of the Tariff Act of 1930, as Amended: Certain Standard Steel Fasteners from the People's Republic of China, dated September 23, 2009 ("Petition").

Consultations

Pursuant to section 702(b)(4)(A)(ii) of the Act, on September 23, 2009, the Department invited representatives of the Government of the PRC for consultations with respect to the CVD petition. On October 13, 2009, the GOC requested that the Department extend the deadline for consultations. The Department responded that it could not extend this deadline for pre-initiation consultations, but would consult with the GOC in the course of this proceeding if initiated, as required by Article 13.2 of the Agreement on Subsidies and Countervailing Measures.

Determination of Industry Support for the Petition

Section 702(b)(1) of the Act requires that a petition be filed on behalf of the domestic industry. Section 702(c)(4)(A) of the Act provides that a petition meets this requirement if the domestic producers or workers who support the petition account for: (i) At least 25 percent of the total production of the domestic like product; and (ii) more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the petition. Moreover, section 702(c)(4)(D) of the Act provides that, if the petition does not establish support of domestic producers or workers accounting for more than 50 percent of the total production of the domestic like product, the Department shall: (i) poll the industry or rely on other information in order to determine if there is support for the petition, as required by subparagraph (A), or (ii) determine industry support using a statistically valid sampling method.

Section 771(4)(A) of the Act defines the "industry" as the producers as a whole of a domestic like product. Thus, to determine whether a petition has the requisite industry support, the statute directs the Department to look to producers and workers who produce the domestic like product. The U.S. International Trade Commission ("ITC"), which is responsible for determining whether "the domestic industry" has been injured, must also determine what constitutes a domestic like product in order to define the industry. While both the Department and the ITC must apply the same statutory definition regarding the domestic like product (section 771(10) of the Act), they do so for different purposes and pursuant to a separate and distinct authority. In addition, the Department's determination is subject to limitations of time and information.

Although this may result in different definitions of the like product, such differences do not render the decision of either agency contrary to law. *See USEC, Inc. v. United States*, 132 F. Supp. 2d 1, 8 (Ct. Int'l Trade 2001), citing *Algoma Steel Corp. Ltd. v. United States*, 688 F. Supp. 639, 644 (Ct. Int'l Trade 1988), *aff'd* 865 F.2d 240 (Fed. Cir. 1989), *cert. denied* 492 U.S. 919 (1989).

Section 771(10) of the Act defines the domestic like product as "a product which is like, or in the absence of like, most similar in characteristics and uses with, the article subject to an investigation under this title." Thus, the reference point from which the domestic like product analysis begins is "the article subject to an investigation" (*i.e.*, the class or kind of merchandise to be investigated, which normally will be the scope as defined in the petition).

With regard to the domestic like product, Petitioner does not offer a definition of domestic like product distinct from the scope of the investigation. Based on our analysis of the information submitted on the record, we have determined that fasteners constitute a single domestic like product and we have analyzed industry support in terms of that domestic like product. For a discussion of the domestic like product analysis in this case, *see* "Countervailing Duty Investigation Initiation Checklist: Certain Standard Steel Fasteners from the People's Republic of China" ("Initiation Checklist"), at Attachment II, Analysis of Industry Support for the Petitions Covering Certain Standard Steel Fasteners from the People's Republic of China, on file in the Central Records Unit ("CRU"), Room 1117 of the main Department of Commerce building.

In determining whether Petitioner has standing (*i.e.*, the domestic workers and producers supporting the Petition account for (1) at least 25 percent of the total production of the domestic like product and (2) more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the Petition), we considered the industry support data contained in the Petition with reference to the domestic like product. To establish industry support, Petitioner provided its production of the domestic like product for the year 2008, and compared this to the estimated total production of the domestic like product for the entire domestic industry. *See* Volume I of the Petition, at 2–3, Exhibit I–10, and Supplement to the AD/CVD Petitions, dated October 6, 2009, at 17–

18, Exhibit I–Supp-6, and Industry Support Supplement, dated October 8, 2009 ("Industry Support Supplement"), at Attachment 1. To estimate 2008 production of the domestic like product, Petitioner used its own data and industry specific knowledge. *See* Industry Support Supplement, at Attachment 1. Petitioner calculated total domestic production based on its own production plus estimates regarding the other producers of the domestic like product in the United States. *Id.* We have relied upon data Petitioner provided for purposes of measuring industry support. For further discussion, *see* Initiation Checklist at Attachment II.

The Department's review of the data provided in the Petition, supplemental submissions, and other information readily available to the Department indicates that Petitioner has established industry support. First, the Petition establishes support from domestic producers (or workers) accounting for more than 50 percent of the total production of the domestic like products and, as such, the Department is not required to take further action in order to evaluate industry support (*e.g.*, polling). *See* section 702(c)(4)(D) of the Act and Initiation Checklist at Attachment II. Second, the domestic producers (or workers) have met the statutory criteria for industry support under section 702(c)(4)(A)(i) of the Act because the domestic producers (or workers) who support the Petition account for at least 25 percent of the total production of the domestic like products. *See* Initiation Checklist at Attachment II. Finally, the domestic producers (or workers) have met the statutory criteria for industry support under section 702(c)(4)(A)(ii) of the Act because the domestic producers (or workers) who support the Petition account for more than 50 percent of the production of the domestic like products produced by that portion of the industry expressing support for, or opposition to, the Petitions. Accordingly, the Department determines that the Petition was filed on behalf of the domestic industry within the meaning of section 702(b)(1) of the Act. *See* Initiation Checklist at Attachment II.

The Department finds that Petitioner filed the Petition on behalf of the domestic industry because it is an interested party as defined in section 771(9)(C) of the Act and has demonstrated sufficient industry support with respect to the CVD investigation that it is requesting the Department initiate. *See* Initiation Checklist at Attachment II.

Injury Test

Because the PRC is a “Subsidies Agreement Country” within the meaning of section 701(b) of the Act, section 701(a)(2) of the Act applies to this investigation. Accordingly, the ITC must determine whether imports of subject merchandise from the PRC materially injure, or threaten material injury to, a U.S. industry.

Allegations and Evidence of Material Injury and Causation

Petitioner alleges that imports of standard steel fasteners from the PRC are benefitting from countervailable subsidies and that such imports are causing, or threaten to cause, material injury to the domestic industry producing certain standard steel fasteners. In addition, Petitioner alleges that subsidized imports exceed the negligibility threshold provided for under section 771(24)(A) of the Act.

Petitioner contends that the industry’s injured condition is illustrated by reduced market share, underselling and price depressing and suppressing effects, increased import penetration, declining sales, reduced production, reduced capacity, increased raw material cost, abandoned product lines, reduced shipments, reduced wages and hours worked, and an overall decline in financial performance. We have assessed the allegations and supporting evidence regarding material injury, threat of material injury, and causation, and we have determined that these allegations are properly supported by adequate evidence and meet the statutory requirements for initiation. *See* Initiation Checklist at Attachment III (Analysis of Injury Allegations and Evidence of Material Injury and Causation).

Initiation of Countervailing Duty Investigation

Section 702(b) of the Act requires the Department to initiate a CVD proceeding whenever an interested party files a petition on behalf of an industry that: (1) Alleges the elements necessary for an imposition of a duty under section 701(a) of the Act; and (2) is accompanied by information reasonably available to the petitioner(s) supporting the allegations.

The Department has examined the CVD petition on standard steel fasteners from the PRC and finds that it complies with the requirements of section 702(b) of the Act. Therefore, in accordance with section 702(b) of the Act, we are initiating a CVD investigation to determine whether manufacturers, producers, or exporters of standard steel

fasteners in the PRC receive countervailable subsidies. For a discussion of evidence supporting our initiation determination, *see* Initiation Checklist.

We are including in our investigation the following programs alleged in the Petition to have provided countervailable subsidies to producers and exporters of the subject merchandise in the PRC:

- A. Preferential Loans and Interest Rates
 1. Policy Loans to Chinese Fasteners Producers
 2. Export Loans
 3. Preferential Lending to Fasteners Producers and Exporters Classified as “Honorably Enterprises”
 4. Preferential Loans as Part of the Northeast Revitalization Program
- B. Government Provision of Goods or Services for Less Than Adequate Remuneration (“LTAR”)
 1. Wire Rod for LTAR
 2. Hot-Rolled Steel for LTAR
 3. Zinc for LTAR
 4. Land-Use Rights for LTAR
- C. Income and Other Direct Taxes
 1. Income Tax Credits for Domestically Owned Companies Purchasing Domestically Produced Equipment
 2. Preferential Income Tax Policy for Enterprises in the Northeast Region
 3. Forgiveness of Tax Arrears for Enterprises in the Old Industrial Bases of Northeast China
- D. Indirect Tax and Tariff Exemption Programs
 1. Export Incentive Payments Characterized as “VAT Rebates”
 2. Import Tariff and VAT Exemptions for Foreign Invested Enterprises (“FIEs”) and Certain Domestic Enterprises Using Imported Equipment in Encouraged Industries
- E. Preferential Income Tax Subsidies for FIEs
 1. “Two Free, Three Half” Tax Exemptions for FIEs
 2. Income Tax Exemption Program for Export-Oriented FIEs
 3. Local Income Tax Exemption and Reduction Programs for “Productive” FIEs
 4. Preferential Tax Programs for FIEs Recognized as High or New Technology Enterprises
 5. Income Tax Subsidies for FIEs Based on Geographic Location
 6. VAT Refunds for FIEs Purchasing Domestically Produced Equipment
- F. Direct Grants
 1. “Five Points, One Line” Program
 2. Export Interest Subsidies
 3. The State Key Technology Renovation Project Fund

4. Export Assistance Grants in Zhejiang Province
5. Subsidies for Development of Famous Export Brands and China World Top Brands
6. Sub-Central Government Programs to Promote Famous Export Brands and China World Top Brands
7. Programs to Rebate Antidumping Legal Fees in Zhejiang and Shenzhen Province

For further information explaining why the Department is investigating these programs, *see* Initiation Checklist.

We are not including in our investigation the following programs alleged to benefit producers and exporters of subject merchandise in the PRC:

1. Preferential Loans for Key Projects and Technologies

In its Petition, Petitioner asserted that some fasteners producers located in Northeastern China may benefit from preferential loans given to their steel suppliers. However, Petitioner did not file an adequate upstream subsidy allegation, nor did Petitioner allege that fasteners producers would be eligible to receive preferential loans under this program directly. Furthermore, in its October 7, 2009 supplemental response, Petitioner allows that it is unlikely that fasteners producers benefited from this program. Accordingly, we do not plan on investigating this program.

2. Electricity for LTAR

Petitioner alleges that the Government of the PRC (“GOC”) is providing a financial benefit of electricity for less than adequate remuneration to steel producers, and that fasteners producers receive an associated downstream benefit within the meaning of Section 771(5)(D)(iii) of the Act. The financial contribution as alleged by Petitioner is an upstream subsidy. Petitioner has not supported the allegation and, consequently, we do not plan to investigate this program.

3. Fixed Assets Investment Orientation Regulatory Tax

Petitioner claims that producers of fasteners in the PRC are exempted from or receive preferential income tax rates on investments in fixed assets. Petitioner has not provided information to demonstrate that fasteners producers would be covered by the relevant legislation. For example, the legislation relating to this program includes specific aspects of the iron and steel production process that are eligible for tax benefits, but it does not include any processes related to production of fasteners. Accordingly, we do not plan

on investigating this program. However, if one of the mandatory respondents chosen in this investigation is part of a vertically integrated steel company, or cross-owned with a primary steel producer, Petitioner may re-allege this program under a timely filed new subsidy allegation, at which time the Department will reconsider the information provided. Accordingly, we do not plan on investigating this program.

4. Tax Reduction for Enterprises Making Little Profit

According to the PRC's World Trade Organization subsidies notification, enterprises with annual taxable incomes between Renminbi ("RMB") 30,000 and 100,000 are eligible for a three percent reduction in their annual income tax rate. Petitioner has not established with reasonably available information that "enterprises making little profit" are a *de jure* specific group because Petitioner has provided no explanation of why companies with access to this program comprise an enterprise or industry, or group of enterprises or industries within the meaning of Section 771(5A) of the Act. Consequently, we do not plan on investigating this program.

5. Income Tax Exemption for Investment in Domestic "Technological Renovation"

Petitioner alleges that, pursuant to the Technological Renovation of Domestic Equipment Corporate Income Tax Exemption Notice, the State Tax Administration provides a tax credit to enterprises for a certain portion of investment in any domestically produced equipment that relates to technology updates. However, in the final determination of certain kitchen appliance shelving and racks from the PRC, the Department investigated this program and found that it does not exist.² Consequently, we do not plan on investigating this program.

6. China's Enforced Undervaluation of Its Currency

Petitioner alleges that the GOC-maintained exchange rate effectively prevents the appreciation of the Chinese currency (RMB) against the U.S. dollar. Therefore, when producers/exporters in the PRC sell their dollars at official foreign exchange banks, as required by law, the producers receive more RMB than they otherwise would if the value of the RMB were set by market

mechanisms. Petitioner describes the benefit conferred as the excess of RMB received, over what would have been received at a market rate ("excess RMB") and alleges specificity within the meaning of Section 771(5A)(B) of the Act by virtue of the fact that "* * * there is a direct and positive correlation between the export activity/export earnings and the amount of subsidy received." Section 771(5A)(B) of the Act describes an export subsidy as "* * * a subsidy that is, in law or fact, contingent upon export performance, alone or as 1 of 2 or more conditions." Petitioner has failed to sufficiently allege that the receipt of the excess RMB is contingent on export or export performance because receipt of the excess RMB is independent of the type of transaction or commercial activity for which the dollars are converted or of the particular company or individuals converting the dollars. Therefore, we do not plan on investigating this program because Petitioner has failed to properly allege the specificity element.

Respondent Selection

For this investigation, the Department expects to select respondents based on U.S. Customs and Border Protection ("CBP") data for U.S. imports during the POI. We intend to release the CBP data under Administrative Protective Order ("APO") to all parties with access to information protected by APO within five days of the announcement of the initiation of this investigation. Interested parties may submit comments regarding the CBP data and respondent selection within seven calendar days of publication of this notice. We intend to make our decision regarding respondent selection within 20 days of publication of this **Federal Register** notice.

Interested parties must submit applications for disclosure under APO in accordance with 19 CFR 351.305(b). Instructions for filing such applications may be found on the Department's Web site at <http://ia.ita.doc.gov/apo>.

Distribution of Copies of the Petition

In accordance with section 702(b)(4)(A)(i) of the Act, a copy of the public version of the Petition has been provided to the Government of the PRC. As soon as and to the extent practicable, we will attempt to provide a copy of the public version of the Petition to each exporter named in the Petition, consistent with section 351.203(c)(2) of the Department's regulations.

ITC Notification

We have notified the ITC of our initiation, as required by section 702(d) of the Act.

Preliminary Determination by the ITC

The ITC will preliminarily determine, within 25 days after the date on which it receives notice of the initiation, whether there is a reasonable indication that imports of subsidized standard steel fasteners from the PRC are causing material injury, or threatening to cause material injury, to a U.S. industry. See section 703(a)(2) of the Act. A negative ITC determination will result in the investigation being terminated; otherwise, the investigation will proceed according to statutory and regulatory time limits.

This notice is issued and published pursuant to section 777(i) of the Act.

Ronald K. Lorentzen,

Acting Assistant Secretary for Import Administration.

Appendix I—Scope of Investigation

The merchandise covered by the investigation consists of certain standard nuts, standard bolts, and standard cap screws, of steel other than stainless steel. Standard nuts, standard bolts, and standard cap screws covered by the investigation may have a variety of finishes, including but not limited to coating in paint, phosphates, and zinc. Standard bolts and standard cap screws covered by the investigation have a shank or thread with an actual and/or nominal diameter between 6 millimeters and 32 millimeters (inclusive). Standard bolts and standard cap screws covered by the investigation also possess a circular or hexagonal head, the surface of which may be flat or rounded (also known as "dome-shaped" or "button-headed"). Standard bolts covered by the investigation may have an attached washer face or the equivalent (*e.g.*, a flanged head or chamfered corners on the underside of a fastener with a hexagonal-shaped head). Standard cap screws covered by the investigation have a permanently-attached washer face. Standard nuts are covered by the investigation if they are suitable for attachment to bolts and/or cap screws covered by the investigation.

Standard bolts, standard cap screws, and standard nuts are covered by the investigation whether imported alone, attached to other subject and/or non-subject merchandise (*e.g.*, tension control assemblies), or unattached and in combination with other subject merchandise and/or non-subject merchandise.

Standard nuts, standard bolts, and standard cap screws meet the requirements of one or more nationally recognized consensus industry standard specifications (including but not limited to those referenced below). Subject merchandise is typically certified to the specifications published by one or more consensus standards organizations such as the following: the American Society for Testing and Materials (ASTM), the Society of Automotive Engineers (SAE), the International Organization for Standardization (ISO), and the Industrial Fasteners Institute. Common specifications to which subject merchandise is certified

² See *Certain Kitchen Shelving and Racks from the People's Republic of China: Final Affirmative Countervailing Duty Determination*, 74 FR 37012 (July 27, 2009), and accompanying Issues and Decision Memorandum at 18.

include, but are not limited to: ASTM A194, ASTM A307, ASTM A325, ASTM A325M, ASTM A354, ASTM A449, ASTM A490, ASTM A563, ASTM F568M, ASTM F1852, ASTM F2280, SAE J429, SAE J1199, ISO 898-1, ISO 898-2, ISO 4759-1, ISO 8992, and comparable foreign and domestic specifications (including, but not limited to, metric versions of specifications such as those listed above).

Excluded from the scope of the investigation are bolts, cap screws, and nuts produced for an original equipment manufacturer (OEM) part number specific to any "automobile" as defined in 49 U.S.C. Section 32901(a)(3), any "work truck" as defined in 49 U.S.C. Section 32901(a)(19), or any "medium-duty passenger vehicle" as defined in 40 C.F.R. Section 86.1803-01 (2009).

Also excluded from the scope of the investigation are bolts, cap screws, and nuts produced for an OEM part number specific to any "aircraft" as defined in 14 CFR 1.1 (2009).

Also excluded from the scope of the investigation are track bolts. Track bolts have a circular, rounded head and a shank which, immediately beneath the head, possesses an oval or elliptical shape, such that the non-round shape would restrict rotational movement of the bolt. Also excluded from the scope of the investigation are carriage bolts. Carriage bolts have a circular, rounded head and a shank which, immediately beneath the head, possesses a non-round shape (e.g., square, finned), such that the non-round shape would restrict rotational movement of the bolt. Also excluded from the scope of the investigation are socket screws. Socket screws have a head with a recessed cavity into which a shaped bit may be inserted to turn and drive the fastener.

Unless explicitly excluded from the scope of the investigation, bolts, cap screws, and nuts meeting the description of subject merchandise are covered by the investigation.

Merchandise covered by the investigation is classified in the Harmonized Tariff Schedule of the United States (HTSUS) under subheadings: 7318.15.2030, 7318.15.2055, 7318.15.2065, 7318.15.8065, 7318.15.8085, and 7318.16.0085. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise under the investigation is dispositive.

[FR Doc. E9-25197 Filed 10-21-09; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[C-533-849]

Commodity Matchbooks From India: Final Affirmative Countervailing Duty Determination

AGENCY: Import Administration, International Trade Administration, Department of Commerce

SUMMARY: The Department of Commerce (the Department) determines that countervailable subsidies are being provided to producers and exporters of commodity matchbooks from India. For information on the estimated subsidy rates, see the "Suspension of Liquidation" section of this notice.

EFFECTIVE DATE: October 22, 2009.

FOR FURTHER INFORMATION CONTACT: Sean Carey or Dana Mermelstein, AD/CVD Operations, Office 6, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230; telephone: (202) 482-3964 and (202) 482-1391, respectively.

SUPPLEMENTARY INFORMATION:

Period of Investigation

The period for which we are measuring subsidies, *i.e.*, the period of investigation (POI), is January 1, 2007 through December 31, 2007.

Case History

The following events have occurred since the publication of the Department's preliminary determination in the **Federal Register**. See *Commodity Matchbooks from India: Preliminary Affirmative Countervailing Duty Determination and Alignment of Final Countervailing Duty Determination with Final Antidumping Duty Determination*, 74 FR 15444 (April 6, 2009). The Department conducted a verification of the Government of India's (GOI) questionnaire responses regarding the administration of the Export Promotion Capital Goods Scheme (EPCGS) on May 4, 2009, in New Delhi, India. See Memorandum to Dana Mermelstein, Program Manager for AD/CVD Operations, Office 6, from Sean Carey, Case Analyst, AD/CVD Operations, Office 6, "Verification of the Questionnaire Responses Submitted by the Government of India," dated August 7, 2009. On May 5 through 8, 2009, the Department verified the information submitted by the sole respondent in this investigation, Triveni Safety Matches Pvt. Ltd. (Triveni), at its corporate headquarters in Mumbai, India. See Memorandum to Dana Mermelstein, Program Manager for AD/CVD Operations, Office 6, from Sean Carey, Case Analyst, AD/CVD Operations, Office 6, "Verification of the Questionnaire Responses Submitted by Triveni Safety Matches Pvt. Ltd.," dated August 7, 2009. The Department released its briefing schedule on August 7, 2009, notifying all parties of the deadlines for submission of case and rebuttal briefs. No case briefs were filed

by any of the interested parties. The memoranda cited above are available at the Department's Central Records Unit (Room 1117 in the HCHB Building) (hereafter referred to as "CRU").

Scope of the Investigation

The scope of this investigation covers commodity matchbooks, also known as commodity book matches, paper matches or booklet matches.¹ Commodity matchbooks typically, but do not necessarily, consist of twenty match stems which are usually made from paperboard or similar material tipped with a match head composed of any chemical formula. The match stems may be stitched, stapled or otherwise fastened into a matchbook cover of any material, on which a striking strip composed of any chemical formula has been applied to assist in the ignition process.

Commodity matchbooks included in the scope of this investigation may or may not contain printing. For example, they may have no printing other than the identification of the manufacturer or importer. Commodity matchbooks may also be printed with a generic message such as "Thank You" or a generic image such as the American Flag, with store brands (e.g., Kroger, 7-Eleven, Shurfine or Giant); product brands for national or regional advertisers such as cigarettes or alcoholic beverages; or with corporate brands for national or regional distributors (e.g., Penley Corp. or Diamond Brands). They all enter retail distribution channels. Regardless of the materials used for the stems of the matches and regardless of the way the match stems are fastened to the matchbook cover, all commodity matchbooks are included in the scope of this investigation. All matchbooks, including commodity matchbooks, typically comply with the United States Consumer Product Safety Commission (CPSC) Safety Standard for Matchbooks, codified at 16 CFR § 1202.1 *et seq.*

The scope of this investigation excludes promotional matchbooks, often referred to as "not for resale," or "specialty advertising" matchbooks, as they do not enter into retail channels and are sold to businesses that provide hospitality, dining, drinking or entertainment services to their customers, and are given away by these businesses as promotional items. Such promotional matchbooks are distinguished by the physical

¹ Such commodity matchbooks are also referred to as "for resale" because they always enter into retail channels, meaning businesses that sell a general variety of tangible merchandise, e.g., convenience stores, supermarkets, dollar stores, drug stores and mass merchandisers.

characteristic of having the name and/or logo of a bar, restaurant, resort, hotel, club, café/coffee shop, grill, pub, eatery, lounge, casino, barbecue or individual establishment printed prominently on the matchbook cover. Promotional matchbook cover printing also typically includes the address and the phone number of the business or establishment being promoted.² Also excluded are all other matches that are not fastened into a matchbook cover such as wooden matches, stick matches, box matches, kitchen matches, pocket matches, penny matches, household matches, strike-anywhere matches (aka "SAW" matches), strike-on-box matches (aka "SOB" matches), fireplace matches, barbecue/grill matches, fire starters, and wax matches.

The merchandise subject to this investigation is properly classified under subheading 3605.00.0060 of the Harmonized Tariff Schedule of the United States (HTSUS). Subject merchandise may also enter under subheading 3605.00.0030 of the HTSUS. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise under investigation is dispositive.

Injury Test

Because India is a "Subsidies Agreement Country" within the meaning of section 701(b) of the Tariff Act of 1930, as amended (the Act), the International Trade Commission (ITC) is required to determine, pursuant to section 701(a)(2) of the Act, whether imports of the subject merchandise from India materially injure, or threaten material injury to, a United States industry. On December 19, 2008, the ITC published its preliminary determination that there is a reasonable indication that an industry in the United States is materially injured by reason of allegedly subsidized imports from the PRC of subject merchandise. See *Commodity Matchbooks from India; Determinations*, 73 FR 77840 (December 19, 2008); and *Commodity Matchbooks from India (Preliminary)*, USITC Pub. 4054, Inv. Nos. 701-TA-459 and 731-TA 1155 (December 2008).

²The gross distinctions between commodity matchbooks and promotional matchbooks may be summarized as follows: (1) if it has no printing, or is printed with a generic message such as "Thank You" or a generic image such as the American Flag, or printed with national or regional store brands or corporate brands, it is commodity; (2) if it has printing, and the printing includes the name of a bar, restaurant, resort, hotel, club, café/coffee shop, grill, pub, eatery, lounge, casino, barbecue, or individual establishment prominently displayed on the matchbook cover, it is promotional.

Analysis of Programs

A complete description and discussion of the programs that the Department investigated are addressed in the Issues and Decision Memorandum for the Final Affirmative Countervailing Duty Determination: Commodity Matchbooks from India, from John M. Andersen, Acting Deputy Assistant Secretary, to Ronald K. Lorentzen, Acting Assistant Secretary, dated October 15, 2009 ("Issues and Decision Memorandum"). Modifications to the calculations based on verification are also discussed in this memorandum. Parties can find this public memorandum in the Department's CRU. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly on the internet at <http://ia.ita.doc.gov/frn/index.html>. The paper copy and electronic version of the Issues and Decision Memorandum are identical in content.

Suspension of Liquidation

In accordance with section 705(c)(1)(B)(i)(I) of the Act, we have calculated an individual subsidy rate for the company under investigation, Triveni, below. Section 705(c)(5)(A)(i) of the Act states that for companies not investigated, we will determine an all others rate equal to the weighted average countervailable subsidy rates established for exporters and producers individually investigated, excluding any zero and *de minimis* countervailable subsidy rates, and any rates determined entirely under section 776 of the Act. As Triveni was the only exporter/manufacturer under investigation, the all others rate is based on Triveni's total subsidy rate calculated for this final determination.

Exporter/Manufacturer	Net Subsidy Rate
Triveni Safety Matches Pvt. Limited	9.88%
All Others	9.88%

In accordance with section 703(d) of the Act, we instructed U.S. Customs and Border Protection to discontinue the suspension of liquidation for countervailing duty purposes for subject merchandise entered on or after August 4, 2009, but to continue the suspension of liquidation of entries made from April 6, 2009 through August 3, 2009.

We will issue a countervailing duty order and reinstate the suspension of liquidation under section 706(a) of the Act if the ITC issues a final affirmative injury determination, and we will require a cash deposit of estimated countervailing duties for such entries of merchandise in the amounts indicated

above. If the ITC determines that material injury, or threat of material injury, does not exist, this proceeding will be terminated and all estimated duties deposited or securities posted as a result of the suspension of liquidation will be refunded or canceled.

ITC Notification

In accordance with section 705(d) of the Act, we will notify the ITC of our determination. In addition, we are making available to the ITC all non-privileged and nonproprietary information related to this investigation. We will allow the ITC access to all privileged and business proprietary information in our files, provided the ITC confirms that it will not disclose such information, either publicly or under an Administrative Protective Order (APO), without the written consent of the Assistant Secretary for Import Administration.

Return or Destruction of Proprietary Information

In the event that the ITC issues a final negative injury determination, this notice will serve as the only reminder to parties subject to an APO of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

This determination is issued and published pursuant to sections 705(d) and 777(i) of the Act.

Dated: October 15, 2009.

Ronald K. Lorentzen,

Acting Assistant Secretary for Import Administration.

[FR Doc. E9-25445 Filed 10-21-09; 8:45 am]

BILLING CODE 3510-DS-S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[Docket No. 070827327-7327-01]

RIN 0648-XS21

Fisheries of the Northeastern United States; Atlantic Surfclam and Ocean Quahog Fisheries; Notice that Vendor Will Provide Year 2010 Cage Tags

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and

Atmospheric Administration (NOAA),
Commerce.

ACTION: Notice of vendor to provide
year 2010 cage tags.

SUMMARY: NMFS informs surfclam and
ocean quahog allocation owners that
they will be required to purchase their
year 2010 cage tags from the National
Band and Tag Company. The intent of
this notice is to comply with regulations
for the Atlantic surfclam and ocean
quahog fisheries and to promote
efficient distribution of cage tags.

ADDRESSES: Written inquiries may be
sent to: Regional Administrator,
National Marine Fisheries Service,
Northeast Regional Office, 55 Great
Republic Drive, Gloucester, MA 01930-
2298.

FOR FURTHER INFORMATION CONTACT:
Anna Macan, Fishery Management
Specialist, (978) 281-9165; fax (978)
281-9135.

SUPPLEMENTARY INFORMATION: The
Federal Atlantic surfclam and ocean
quahog fishery regulations at 50 CFR
648.75(b) authorize the Regional
Administrator of the Northeast Region,
NMFS, to specify in the **Federal
Register** a vendor from whom cage tags,
required under the Atlantic Surfclam
and Ocean Quahog Fishery Management
Plan (FMP), shall be purchased. Notice
is hereby given that National Band and
Tag Company of Newport, Kentucky, is
the authorized vendor of cage tags
required for the year 2010 Federal
surfclam and ocean quahog fisheries.
Detailed instructions for purchasing
these cage tags will be provided in a
letter to allocation owners in these
fisheries from NMFS within the next
several weeks.

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

Dated: October 16, 2009.

Emily H. Menashes,

*Acting Director, Office of Sustainable
Fisheries, National Marine Fisheries Service.*
[FR Doc. E9-25468 Filed 10-21-09; 8:45 am]

BILLING CODE 3510-22-S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[Docket No. 070717342-7713-02]

RIN 0648-XS19

Magnuson-Stevens Fishery Conservation and Management Act Provisions; Fisheries of the Northeastern United States; Atlantic Surfclam and Ocean Quahog Fishery; 2010 Fishing Quotas for Atlantic Surfclams and Ocean Quahogs

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

ACTION: Notice.

SUMMARY: NMFS is announcing that the
quotas for the Atlantic surfclam and
ocean quahog fisheries for 2010 remain
status quo. Regulations governing these
fisheries require NMFS to notify the
public in the **Federal Register** of the
allowable harvest levels for Atlantic
surfclams and ocean quahogs from the
Exclusive Economic Zone if the
previous year's quota specifications
remain unchanged.

ADDRESSES: Written inquiries may be
sent to: Regional Administrator,
National Marine Fisheries Service,
Northeast Regional Office, 55 Great
Republic Drive, Gloucester, MA 01930-
2298.

FOR FURTHER INFORMATION CONTACT:
Anna Macan, Fishery Management
Specialist, (978) 281-9177; fax (978)
281-9135.

SUPPLEMENTARY INFORMATION: The
fishery management plan for the
Atlantic surfclam and ocean quahog
fisheries requires that NMFS issue
notification in the **Federal Register** of
the upcoming year's quota, even in
cases where the quota remains
unchanged from the previous year. At
its June 2009 meeting, the Mid-Atlantic
Fishery Management Council voted that
no action be taken to change the quota
specifications for Atlantic surfclams and
ocean quahogs for the 2010 fishing year
(January 1 through December 31, 2010),
and recommended maintaining the 2008
quota levels of 3.4 million bu (181
million L) for Atlantic surfclams, 5.333
million bu (284 million L) for ocean
quahogs, and 100,000 Maine bu (3.524
million L) for Maine ocean quahogs, as
announced in the **Federal Register** on
January 4, 2008 (73 FR 820).

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

Dated: October 16, 2009.

Emily H. Menashes,

*Acting Director, Office of Sustainable
Fisheries, National Marine Fisheries Service.*
[FR Doc. E9-25466 Filed 10-21-09; 8:45 am]

BILLING CODE 3510-22-S

DEPARTMENT OF COMMERCE

National Telecommunications and Information Administration

Broadband Data Transparency Workshop

AGENCY: National Telecommunications
and Information Administration, U.S.
Department of Commerce

ACTION: Notice of Public Meeting.

SUMMARY: The National
Telecommunications and Information
Administration (NTIA) will host a
public meeting regarding data related to
broadband Internet access that the
agency collects, data needs of
researchers, and future broadband
research.

DATES: The meeting will be held on
October 30, 2009, from 1:00 p.m. to 3:00
p.m. Eastern Daylight Time.

ADDRESSES: The meeting will be held at
the U.S. Department of Commerce,
National Telecommunications and
Information Administration, 1401
Constitution Avenue, NW, Herbert C.
Hoover Building, Room 4830,
Washington, DC 20230 (please enter at
14th Street). The disability accessible
entrance is located at the 14th Street
Aquarium Entrance. Any change in the
location will be posted on NTIA's
website (www.ntia.doc.gov) prior to the
meeting.

FOR FURTHER INFORMATION CONTACT: For
further information regarding the
meeting, contact James McConnaughey,
NTIA, at (202) 482-1880 or
JMcConnaughey@ntia.doc.gov.

SUPPLEMENTARY INFORMATION: President
Obama is committed to the expansion of
broadband Internet access across the
United States as a necessary part of the
foundation for long term economic
stability and prosperity.¹ The National
Telecommunications and Information
Administration (NTIA) is the President's
principal adviser on domestic and
international communications policies
pertaining to the Nation's economic and
technological advancement. In order to
achieve the technology and broadband

¹ See Guiding Principles, "Innovation in the
Economy: Drive Economic Growth and Solve
National Problems by Deploying a 21st Century
Information Infrastructure," [http://
www.whitehouse.gov/issues/technology](http://www.whitehouse.gov/issues/technology).

goals of the Administration, NTIA is working with the Federal Communications Commission (FCC), the Department of Agriculture's Rural Utilities Service (RUS), and other stakeholders to develop and implement economic and regulatory policies that foster broadband Internet access deployment and adoption. Current and detailed data on broadband Internet use and access by U.S. households is critical to allow policymakers not only to gauge progress made to date, but to identify problem areas.

The purpose of the public meeting is to provide information to the research community regarding the type and availability of broadband data that may be made publicly available for use by the research community, and to hear from this research community with respect to their data needs. NTIA is authorized to conduct studies and evaluations concerning communications research and development and for 15 years, has developed and analyzed Internet data (including more recently the high-speed variety). These activities have provided essential data for prudent policymaking in this area, including fueling the needs of the research community whose work could be invaluable inputs for sound policies. NTIA currently collects broadband related data from several sources. Pursuant to the American Recovery and Reinvestment Act of 2009 (Recovery Act) and the Broadband Data Improvement Act (BDIA), two broadband initiatives within NTIA, the Broadband Technology Opportunities Program (BTOP) and the State Broadband Data and Development Grant Program (State Broadband Data Program), are accumulating a variety of data.² Under the State Broadband Data Program in particular, this includes data that will populate a comprehensive, interactive, and searchable nationwide inventory map of existing broadband service capability and availability in the United States that depicts the geographic extent to which broadband service capability is deployed, available, and adopted from a commercial or public provider throughout each State.³

In October 2009, the Census Bureau collected through the Current Population Survey (CPS) data based on questions that NTIA sponsored and developed to provide up-to-date information on the extent of U.S.

broadband adoption and the major reasons why current non-users choose not to adopt. Data have been generated by several demographic and geographic categories and must be weighted and appropriately aggregated before release. Census periodically releases public use files containing the raw data collected.

These various data may be made publicly available for use by the research community to conduct economic, financial, demographic, and other studies. Such release, however, may be limited by such Federal disclosure laws as the Freedom of Information Act and the Trade Secrets Act.

Specific information regarding the status of and data from specific applications for the Broadband Technology Opportunities Program (BTOP) and the State Broadband Data and Development Grant Program (State Broadband Data Program) will not be discussed at the meeting.

Matters to Be Considered: The meeting will include a discussion of the following topics:

1. The types and frequency of broadband Internet access data that NTIA can compile through its ongoing programs and research that will be useful to the research community. For example, NTIA has categories of data from the BTOP and State Broadband Data Program and is gathering information through the next CPS that may be useful to the research community;

2. The current sources of data available to the research community for research related to broadband Internet access;

3. The economic, social, policy, or other areas that research related to broadband Internet access can inform;

4. The emergent themes, trends, and new directions within the research community regarding broadband Internet access data;

5. The data format preferred by researchers including those for distributing broadband-related data on the Web to promote maximum transparency for researchers and the interested public; and

6. The legal requirements regarding the agency's collection of and dissemination of data from third parties.

Time and Date: The meeting will be held on October 30, 2009, from 1:00 p.m. to 3:00 p.m. Eastern Daylight Time. The times and the agenda topics are subject to change. The meeting may be webcast. Please refer to NTIA's web site, <http://www.ntia.doc.gov>, for the most up-to-date meeting agenda and webcast information.

Place: The meeting will be held at the U.S. Department of Commerce, 1401 Constitution Avenue, NW, Room 4830, Washington, DC 20230. The meeting will be open to the public and press on a first-come, first-served basis. Space is limited. Attendees should bring a photo ID and arrive early to clear security. The public meeting is physically accessible to people with disabilities. Individuals requiring accommodations, such as sign language interpretation or other ancillary aids, are asked to notify Mr. McConnaughey at (202) 482-1880 or JMcConnaughey@ntia.doc.gov, at least five (5) business days before the meeting.

Dated: October 19, 2009.

Kathy D. Smith,

Chief Counsel, National Telecommunications and Information Administration.

[FR Doc. E9-25447 Filed 10-21-09; 8:45 am]

BILLING CODE 3510-60-S

COMMODITY FUTURES TRADING COMMISSION

Notice of Intent, Pursuant to the Authority in Section 2(h)(7) of the Commodity Exchange Act and Commission Rule 36.3(c)(3), To Undertake a Determination Whether the NWP Rockies Financial Basis Contract, Offered for Trading on the IntercontinentalExchange, Inc., Performs a Significant Price Discovery Function

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of action and request for comment.

SUMMARY: The Commodity Futures Trading Commission ("CFTC" or "Commission") is undertaking a review to determine whether the NWP¹ Rockies Financial Basis ("NWR") contract, offered for trading on the IntercontinentalExchange, Inc. ("ICE"), an exempt commercial market ("ECM") under Sections 2(h)(3)-(5) of the Commodity Exchange Act ("CEA" or the "Act"), performs a significant price discovery function. Authority for this action is found in section 2(h)(7) of the CEA and Commission rule 36.3(c) promulgated thereunder. In connection with this evaluation, the Commission invites comment from interested parties.

DATES: Comments must be received on or before November 6, 2009.

ADDRESSES: Comments may be submitted by any of the following methods:

¹ The acronym "NWP" indicates the Northwest Pipeline.

² Broadband Data Improvement Act, Pub. Law No. 110-385, 122 Stat. 4096, section 106(b) (2008). The Secretary delegated his authority to meet the obligations of section 106 of the BDIA to the Assistant Secretary for Communications and Information on April 9, 2009.

³ Recovery Act, section 6001(l), 123 Stat. at 516.

- Follow the instructions for submitting comments. *Federal eRulemaking Portal*: <http://www.regulations.gov>.

- *E-mail*: secretary@cftc.gov. Include NWP Rockies Financial Basis (NWR) Contract in the subject line of the message.

- *Fax*: (202) 418-5521.

- *Mail*: Send to David A. Stawick, Secretary, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

- *Courier*: Same as mail above.

All comments received will be posted without change to <http://www.CFTC.gov/>.

FOR FURTHER INFORMATION CONTACT:

Gregory K. Price, Industry Economist, Division of Market Oversight, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Telephone: (202) 418-5515. Email: gprice@cftc.gov; or Susan Nathan, Senior Special Counsel, Division of Market Oversight, same address. Telephone: (202) 418-5133. E-mail: snathan@cftc.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

On March 16, 2009, the CFTC promulgated final rules implementing provisions of the CFTC Reauthorization Act of 2008 ("Reauthorization Act")² which subjects ECMs with significant price discovery contracts ("SPDCs") to self-regulatory and reporting requirements, as well as certain Commission oversight authorities, with respect to those contracts. Among other things, these rules and rule amendments revise the information-submission requirements applicable to ECMs, establish procedures and standards by which the Commission will determine whether an ECM contract performs a significant price discovery function, and provide guidance with respect to compliance with nine statutory core principles applicable to ECMs with SPDCs. These rules became effective on April 22, 2009.

In determining whether an ECM's contract is or is not a SPDC, the Commission will evaluate the contract's material liquidity, price linkage to other contracts, potential for arbitrage with other contracts traded on designated contract markets or derivatives transaction execution facilities, use of the ECM contract's prices to execute or settle other transactions, and other factors.

In order to facilitate the Commission's identification of possible SPDCs, Commission rule 36.3(c)(2) requires that an ECM operating in reliance on section 2(h)(3) promptly notify the Commission and provide supporting information or data concerning any contract: (i) that averaged five trades per day or more over the most recent calendar quarter; and (ii) (A) for which the ECM sells price information regarding the contract to market participants or industry publications; or (B) whose daily closing or settlement prices on 95 percent or more of the days in the most recent quarter were within 2.5 percent of the contemporaneously determined closing, settlement, or other daily price of another agreement.

II. Determination of a SPDC

A. The SPDC Determination Process

Commission rule 36.3(c)(3) establishes the procedures by which the Commission makes and announces its determination on whether a specific ECM contract serves a significant price discovery function. Under those procedures, the Commission will publish a notice in the **Federal Register** that it intends to undertake a determination as to whether the specified agreement, contract, or transaction performs a significant price discovery function and to receive written data, views, and arguments relevant to its determination from the ECM and other interested persons.³ After prompt consideration of all relevant information,⁴ the Commission will, within a reasonable period of time after the close of the comment period, issue an order explaining its determination. Following the issuance of an order by the Commission that the ECM executes or trades an agreement, contract, or transaction that performs a significant price discovery function, the ECM must demonstrate, with respect to that agreement, contract, or transaction, compliance with the core principles under section 2(h)(7)(C) of the CEA⁵ and the applicable provisions of Part 36.

³ The Commission may commence this process on its own initiative or on the basis of information provided to it by an ECM pursuant to the notification provisions of Commission rule 36.3(c)(2).

⁴ Where appropriate, the Commission may choose to interview market participants regarding their impressions of a particular contract. Further, while they may not provide direct evidentiary support with respect to a particular contract, the Commission may rely for background and context on resources such as its October 2007 *Report on the Oversight of Trading on Regulated Futures Exchanges and Exempt Commercial Markets* ("ECM Study"). http://www.cftc.gov/stellent/groups/public/@newsroom/documents/file/pr5403-07_ecmreport.pdf.

⁵ U.S.C. 2(h)(7)(C).

If the Commission's order represents the first time it has determined that one of the ECM's contracts performs a significant price discovery function, the ECM must submit a written demonstration of its compliance with the core principles within 90 calendar days of the date of the Commission's order. For each subsequent determination by the Commission that the ECM has an additional SPDC, the ECM must submit a written demonstration of its compliance with the core principles within 30 calendar days of the Commission's order.

B. NWP Rockies Financial Basis Contract

The NWR contract is cash settled based on the difference between the bidweek price index for a particular calendar month at the NWP, Rockies hub, as published by Platts in its *Inside IFERC's Gas Market Report*, and the final settlement price of the New York Mercantile Exchange's (NYMEX's) physically-delivered Henry Hub natural gas futures contract for the same calendar month. The Platts bidweek price is computed from fixed-price, bilateral transactions executed during the last five business days of a given month, where the transactions specify the delivery of natural gas at the NWP, Rockies hub, during the following calendar month. The price index is computed as the volume-weighted average of the applicable natural gas transactions. Bidweek prices are published on the first business day of the month in which the gas flows. The size of the NWR contract is 2,500 mmBtu, and the unit of trading is any multiple of 2,500 mmBtu. The NWR contract is listed for up to 120 calendar months commencing with the next calendar month.

Based upon a required quarterly notification filed on July 27, 2009 (mandatory under Rule 36.3(c)(2)), the ICE reported that, with respect to its NWR contract, the total number of trades was 3,013 in the second quarter of 2009, resulting in a daily average of 47.1 trades. During the same period, the NWR contract had a total trading volume of 276,187 contracts and an average daily trading volume of 4,315.4 contracts. Moreover, the open interest as of June 30, 2009, was 349,931 contracts.

It appears that the NWR contract may satisfy the material liquidity, price linkage, and material price reference factors for SPDC determination. With respect to material liquidity, trading in the NWR contract averaged more than 4,000 contracts on a daily basis, with nearly 50 separate transactions each day. In addition, the open interest in the

² 74 FR 12178 (Mar. 23, 2009); these rules became effective on April 22, 2009.

subject contract was substantial. In regard to price linkage, the final settlement of the NWR contract is based, in part, on the final settlement price of the NYMEX's physically-delivered natural gas contract, where the NYMEX is registered with the Commission as a designated contract market ("DCM"). In regard to material price reference, while it did not specifically address the natural gas contracts under review, the ECM Study stated that, in general, market participants view the ICE as a price discovery market for certain natural gas contracts. Natural gas contracts based on actively-traded hubs are transacted on the ICE's electronic trading platform, with the remainder being completed over-the-counter and potentially submitted for clearing by voice brokers. In addition, the ICE sells its price data to market participants in a number of different packages which vary in terms of the hubs covered, time periods, and whether the data are daily only or historical. For example, the ICE offers the "West Gas End of Day" and "OTC Gas End of Day" data packages with access to all price data or just 12, 24, 36, or 48 months of historical data.

III. Request for Comment

In evaluating whether an ECM's agreement, contract, or transaction performs a significant price discovery function, section 2(h)(7) of the CEA directs the Commission to consider, as appropriate, four specific criteria: Price linkage, arbitrage, material price reference, and material liquidity. As it explained in Appendix A to the Part 36 rules,⁶ the Commission, in making SPDC determinations, will apply and weigh each factor, as appropriate, to the specific contract and circumstances under consideration.

As part of its evaluation, the Commission will consider the written data, views, and arguments from any ECM that lists the potential SPDC and from any other interested parties. Accordingly, the Commission requests comment on whether the ICE's NWR contract performs a significant price discovery function. Commenters' attention is directed particularly to Appendix A of the Commission's Part 36 rules for a detailed discussion of the factors relevant to a SPDC determination. The Commission notes that comments which analyze the contracts in terms of these factors will be especially helpful to the determination process. In order to determine the relevance of comments received, the Commission requests that commenters explain in what capacity

are they knowledgeable about one or several of the subject contracts.

IV. Related Matters

A. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 ("PRA")⁷ imposes certain requirements on federal agencies, including the Commission, in connection with their conducting or sponsoring any collection of information, as defined by the PRA. Certain provisions of final Commission rule 36.3 impose new regulatory and reporting requirements on ECMs, resulting in information collection requirements within the meaning of the PRA; OMB previously has approved and assigned OMB control number 3038-0060 to this collection of information.

B. Cost-Benefit Analysis

Section 15(a) of the CEA⁸ requires the Commission to consider the costs and benefits of its actions before issuing an order under the Act. By its terms, section 15(a) does not require the Commission to quantify the costs and benefits of such an order or to determine whether the benefits of such an order outweigh its costs; rather, it requires that the Commission "consider" the costs and benefits of its action. Section 15(a) further specifies that the costs and benefits shall be evaluated in light of five broad areas of market and public concern: (1) Protection of market participants and the public; (2) efficiency, competitiveness, and financial integrity of futures markets; (3) price discovery; (4) sound risk management practices; and (5) other public interest considerations.

The bulk of the costs imposed by the requirements of Commission Rule 36.3 relate to significant and increased information-submission and reporting requirements adopted in response to the Reauthorization Act's directive that the Commission take an active role in determining whether contracts listed by ECMs qualify as SPDCs. The enhanced requirements for ECMs will permit the Commission to acquire the information it needs to discharge its newly-mandated responsibilities and to ensure that ECMs with SPDCs are identified as entities with the elevated status of registered entity under the CEA and are in compliance with the statutory terms of the core principles of section 2(h)(7)(C) of the Act. The primary benefit to the public is to enable the Commission to discharge its statutory obligation to monitor for the presence of SPDCs and extend its oversight to the trading of SPDCs.

Issued in Washington, DC, on October 14, 2009 by the Commission.

David A. Stawick,

Secretary of the Commission.

[FR Doc. E9-25239 Filed 10-21-09; 8:45 am]

BILLING CODE P

CONSUMER PRODUCT SAFETY COMMISSION

Establishment of a Public Consumer Product Safety Incident Database; Notice of Hearing

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of public hearing.

SUMMARY: The Consumer Product Safety Commission (Commission) will conduct a public hearing to receive views from all interested parties on Section 212 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), Establishment of a Public Consumer Product Safety Incident Database. Participation by members of the public is invited. Oral presentations concerning the Commission's implementation of Section 212 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), Establishment of a Public Consumer Product Safety Incident Database, will become part of the public record.

DATES: The hearing will begin at 9 a.m. on November 10, 2009. Requests to make oral presentations and the written text of any oral presentations must be received by the Office of the Secretary not later than 5 p.m. Eastern Standard Time (EST) on November 3, 2009.

ADDRESSES: The hearing will be in the Hearing Room, 4th Floor of the Bethesda Towers Building, 4330 East West Highway, Bethesda, Maryland 20814. Requests to make oral presentations can be made online at <http://www.cpsc.gov/cgibin/dbmeeting.aspx> or, send an e-mail, call, or write Todd A. Stevenson, Office of the Secretary, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, Maryland 20814; e-mail cpssc-os@cpssc.gov; telephone (301) 504-7923; facsimile (301) 504-0127 not later than 5 p.m. EST on November 3, 2009. Texts of oral presentations should be captioned "Establishment of a Public Consumer Product Safety Incident Database" and sent by electronic mail (e-mail) to cpssc-os@cpssc.gov, or mailed or delivered to the Office of the Secretary, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, Maryland 20814, not later than 5 p.m. EST on November 3, 2009.

⁶ 17 CFR 36, Appendix A.

⁷ 44 U.S.C. 3507(d).

⁸ 7 U.S.C. 19(a).

FOR FURTHER INFORMATION CONTACT: For information about the hearing or to request an opportunity to make an oral presentation, please register online at <http://www.cpsc.gov/cgibin/dbmeeting.aspx> or, send an e-mail, call, or write Todd A. Stevenson, Office of the Secretary, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, Maryland 20814; e-mail cpsecos@cpsec.gov; telephone (301) 504-7923; facsimile (301) 504-0127. An electronic copy of the CPSC "Report to Congress Pursuant to Section 212 of the Consumer Product Safety Improvement Act of 2008, Implementation of a Searchable Consumer Product Safety Incident Database" can be found at <http://www.cpsc.gov/about/cpsia/sect212.html>.

SUPPLEMENTARY INFORMATION: On August 14, 2008, the Consumer Product Safety Improvement Act of 2008 (Pub. L. 110-314) became law. Section 212 of the CPSIA amended the Consumer Product Safety Act (CPSA) to create a new section 6A, titled "Publicly Available Consumer Product Safety Information Database." Section 6A(a)(1) of the CPSA states that the Commission, subject to appropriations, shall "establish and maintain a database on the safety of consumer products, and other products or substances" regulated by the Commission. The statute declares that the database must be publicly available, searchable, and accessible through the Commission's Web site.

The Commission will conduct a public hearing on November 10, 2009, to hear oral comments from interested parties concerning the Commission's establishment of a searchable consumer product safety incident database.

Persons who desire to make oral presentations at the hearing on November 10, 2009, should register online at <http://www.cpsc.gov/cgibin/dbmeeting.aspx> or, send an e-mail, call, or write Todd A. Stevenson, Office of the Secretary, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, Maryland 20814, e-mail cpsecos@cpsec.gov, telephone (301) 504-7923, facsimile (301) 504-0127 not later than 5 p.m. EST on November 3, 2009. Presentations should be limited to approximately ten minutes.

Persons desiring to make presentations must submit the text of their presentations to the Office of the Secretary not later than 5 p.m. EST on November 3, 2009. The Commission reserves the right to impose further time limitations on all presentations and further restrictions to avoid duplication of presentations. The hearing will begin

at 9 a.m. EST on November 10, 2009, and will conclude the same day.

Dated: October 16, 2009.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. E9-25420 Filed 10-21-09; 8:45 am]

BILLING CODE 6355-01-P

DEPARTMENT OF DEFENSE

Defense Logistics Agency

Membership of the Defense Logistics Agency (DLA) Senior Executive Service (SES) Performance Review Board (PRB)

AGENCY: Defense Logistics Agency, Department of Defense.

ACTION: Notice of membership—2009 DLA PRB.

SUMMARY: This notice announces the appointment of members to the Defense Logistics Agency Senior Executive Service (SES) Performance Review Board (PRB). The publication of PRB composition is required by 5 U.S.C. 4314(c)(4). The PRB provides fair and impartial review of Senior Executive Service performance appraisals and makes recommendations to the Director, Defense Logistics Agency (DLA), with respect to pay level adjustments and performance awards and other actions related to management of the SES cadre.

DATES: *Effective Date:* September 16, 2009.

ADDRESSES: Defense Logistics Agency, 8725 John J. Kingman Road, Suite 2533, Fort Belvoir, Virginia 22060-6221.

FOR FURTHER INFORMATION CONTACT: Ms. Julie Brown, SES Program Manager, Human Resources (J-1), Defense Logistics Agency, Department of Defense, (703) 767-5041.

SUPPLEMENTARY INFORMATION: In accordance with 5 U.S.C. 4314(c)(4), the following are the names and titles of DLA career executives appointed to serve as members of the SES PRB. Members will serve a 12-month term, which begins on September 16, 2009.

PRB Chair: Major General Timothy McHale, USA.

Members: Vacant, Director, Human Resources (Non-Voting Member); Mr. J. Anthony Poleo, Director, Financial Operations; Ms. Mae DeVincentis, Director, Information Operations.

A.S. Thompson,

Director, Defense Logistics Agency.

[FR Doc. E9-25300 Filed 10-21-09; 8:45 am]

BILLING CODE 3620-01-M

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

SUMMARY: The Director, Information Collection Clearance Division, Regulatory Information Management Services, Office of Management, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before December 21, 2009.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Director, Information Collection Clearance Division, Regulatory Information Management Services, Office of Management, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g. new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment.

The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology.

Dated: October 19, 2009.
Angela C. Arrington,
*Director, Information Collection Clearance
 Division, Regulatory Information
 Management Services, Office of Management.*

Federal Student Aid

Type of Review: Revision.
Title: National Student Loan Data System (NSLDS).
Frequency: Monthly; Quarterly Semi-Annually; Weekly.
Affected Public: Businesses or other for-profit; Not-for-profit institutions; Private Sector; State, Local, or Tribal Gov't, SEAs or LEAs.

Reporting and Recordkeeping Hour Burden:
Responses: 40,872.
Burden Hours: 157,456.

Abstract: The U.S. Department of Education will collect data from postsecondary schools and guaranty agencies (GAs) about Federal Perkins, Federal Family Education, and William D. Ford Direct Student Loans to be used to determine eligibility for Title IV student financial aid.

Requests for copies of the proposed information collection request may be accessed from <http://edicsweb.ed.gov>, by selecting the "Browse Pending Collections" link and by clicking on link number 4158. When you access the information collection, click on "Download Attachments" to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue, SW., LBJ, Washington, DC 20202-4537. Requests may also be electronically mailed to ICDocketMgr@ed.gov or faxed to 202-401-0920. Please specify the complete title of the information collection when making your request.

Comments regarding burden and/or the collection activity requirements should be electronically mailed to ICDocketMgr@ed.gov. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal

Information Relay Service (FIRS) at 1-800-877-8339.
 [FR Doc. E9-25463 Filed 10-21-09; 8:45 am]
BILLING CODE 4000-01-P

DEPARTMENT OF EDUCATION

**Office of Postsecondary Education;
 Overview Information Student Support Services (SSS) Program; Notice Inviting Applications for New Awards for Fiscal Year (FY) 2010**

Catalog of Federal Domestic Assistance (CFDA) Number: 84.042A

Dates:
Applications Available: October 22, 2009.

Deadline for Transmittal of Applications: December 7, 2009.

Deadline for Intergovernmental Review: February 4, 2010.

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The purpose of the SSS Program is to increase the number of disadvantaged low-income college students, first generation college students, and college students with disabilities in the United States who successfully complete a program of study at the postsecondary level. The support services provided should increase the retention and graduation rates for these students and facilitate their transfer from two-year to four-year colleges and universities. The support services provided should also foster an institutional climate supportive of the success of students who are limited English proficient, students from groups that are traditionally underrepresented in postsecondary education, students with disabilities, students who are homeless children and youths, students who are in foster care or are aging out of the foster care system, and other disconnected students. Student Support Services should also improve the

financial and economic literacy of students.

Program Authority: 20 U.S.C. 1070a-11 and 20 U.S.C. 1070a-14.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 74, 75, 77, 79, 80, 82, 84, 85, 86, 97, 98 and 99. (b) The regulations for this program in 34 CFR part 646.

Note: The regulations in 34 CFR part 79 apply to all applicants except federally recognized Indian tribes.

Note: The regulations in 34 CFR part 86 apply to institutions of higher education only.

Note: The regulations in 34 CFR part 646 apply to this competition except to the extent such regulations conflict with Sections 402A and 402D of the Higher Education Act of 1965, as amended by the Higher Education Opportunity Act of 2008 (HEA).

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: The Administration has requested \$848,089,000 to fund the Federal TRIO Programs, of which, \$268,905,822 has been allocated for new awards for the SSS Program for FY 2010. The actual level of funding, if any, depends on final Congressional action. However, we are inviting applications to allow enough time to complete the grant process if Congress appropriates funds for the Federal TRIO Programs.

Estimated Range of Awards: \$220,000-\$360,000.

Estimated Average Size of Awards: \$308,732.

Maximum Award: We will reject any application that proposes a budget exceeding the maximum amount listed for a single budget period of 12 months.

For Applicants Not Currently Receiving an SSS Program Grant

Type of project	Maximum amount*
Regular SSS Project Serving a Minimum of 140 Student Participants	\$220,000
Regular SSS Project Serving a Minimum of 100 Student Participants with Disabilities	220,000
English as a Second Language (ESL) SSS Project Serving a Minimum of 140 Student Participants	220,000
Science, Technology, Engineering and Mathematics (STEM) SSS Project Serving a Minimum of 120 Student Participants ...	220,000
Health Sciences SSS Project Serving a Minimum of 120 Student Participants	200,000
Teacher Preparation SSS Project Serving a Minimum of 140 Student Participants	220,000

*Note: For any project that will serve less than the minimum number of student participants identified, the maximum award amount that may be requested is an amount equal to \$1,500 per student participant.

For Applicants Currently Receiving an SSS Program Grant

The maximum award amount is the greater of:

- (a) \$220,000 or
- (b) An amount equal to 103 percent of the applicant's base grant award amount

for FY 2008 or 2009, whichever is greater.

Note 1: In calculating the applicant's base grant award amount for FY 2009, the one-

time grant aid supplement awarded in FY 2009 cannot be added to the FY 2009 base grant award amount.

Note 2: For an applicant currently receiving an individual SSS Program grant that has merged into another institution of higher education that is also receiving an individual SSS Program grant, the maximum award amount for the applicant (the merged institution) is an amount equal to 103 percent of the combined FY 2008 or FY 2009 base grant award amounts for both institutions, whichever is greater.

Estimated Number of New Awards: 871.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 60 months.

III. Eligibility Information

1. *Eligible Applicants:* Institutions of higher education or combinations of institutions of higher education.

2. *Cost Sharing or Matching:* Section 402D(d)(4) of the HEA requires that all successful applicants that use SSS Program funds to provide grant aid to students pursuant to Section 402D(d)(1) of the HEA must provide matching funds, in cash, from non-Federal funds, in an amount that is not less than 33 percent of the total amount of the SSS Program funds used for this aid. This matching requirement does not apply to a grant recipient that is an institution of higher education eligible to receive funds under Part A or Part B of Title III or under Title V of the HEA.

3. *Other:* An applicant may submit multiple applications if each separate application describes a project that will serve a different campus or a different population (Section 402A(c)(5) of the HEA). Under section 402A(h)(1) of the HEA, the term "different campus" means a site of an institution of higher education that—(1) is geographically apart from the main campus of the institution; (2) is permanent in nature; and (3) offers courses in educational programs leading to a degree, certificate, or other recognized educational credential (Section 402A(h)(1) of the HEA).

Under Section 402A(h)(2) of the HEA, the term "different population" means a group of individuals that an eligible entity desires to serve through a SSS grant that is separate and distinct from any other population that the entity has applied to serve using Federal TRIO Program funds, or, while sharing some of the same needs as another population that the eligible entity has applied to serve using Federal TRIO Program funds, has distinct needs for specialized services. To implement the requirement in Section 402A(h)(2) for this

competition, the Secretary is designating the populations to be served as: participants who meet the specific requirements for SSS services ("regular SSS grants"), participants with disabilities ("disabled grants"), participants who need ESL services ("ESL grants"), participants receiving services in the STEM fields ("STEM grants"), participants receiving services in the Health Sciences fields ("Health Sciences grants") and participants receiving Teacher Preparation services ("Teacher Preparation grants"). These different populations need different types of services. Accordingly, as noted in the *Maximum Award* section, the Secretary has determined that projects serving these different populations should be subject to different maximum award amounts and different standards for the minimum number of participants. An applicant may submit more than one application as long as each application serves a different population. Any applicant who submits more than one application must submit a justification as to why the different population of participants cannot be served by the project in the applicant's other application(s).

IV. Application and Submission Information

1. *Address to Request Application Package:* Deborah Walsh, U.S. Department of Education, 1990 K Street, NW., Room 7000, Washington, DC 20006–8510. Telephone: (202) 502–7600 or by e-mail: TRIO@ed.gov.

If you use a telecommunications device for the deaf (TDD), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

Individuals with disabilities can obtain a copy of the application package in an accessible format (e.g., braille, large print, audiotape, or computer diskette) by contacting the program contact person listed in this section.

2. *Content and Form of Application Submission:* Requirements concerning the content of an application, together with the forms you must submit, are in the application package for this program.

Page Limit: The application narrative (Part III of the application) is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. You must limit the application narrative (Part III) to no more than 65 pages using the following standards:

- A "page" is 8.5" × 11", on one side only, with 1" margins at the top, bottom, and both sides. Page numbers and an identifier may be within the 1" margin.

- Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions; however, you may single space all text in charts, tables, figures, and graphs.

- Use a font that is either 12 point or larger, or no smaller than 10 pitch (characters per inch).

- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial. An application submitted in any other font (including Times Roman and Arial Narrow) will not be accepted.

The page limit does not apply to Part I, the Application for Federal Assistance Face Sheet (SF 424); Part II, the budget information summary form (ED Form 524); SSS Program Profile; the one-page Project Abstract narrative; and the assurances and certifications. The page limit also does not apply to a table of contents. If you include any attachments or appendices, these items will be counted as part of Part III, the application narrative, for purposes of the page-limit requirement. You must include your complete response to the selection criteria, which also includes the budget narrative in Part III, the application narrative. We will reject your application if you exceed the page limit.

3. *Submission Dates and Times:* *Applications Available:* October 22, 2009.

Deadline for Transmittal of Applications: December 7, 2009.

Applications for grants under this program must be submitted electronically using the Electronic Grant Application System (e-Application) accessible through the Department's e-Grants site. For information (including dates and times) about how to submit your application electronically, or in paper format by mail or hand delivery if you qualify for an exception to the electronic submission requirement, please refer to Section IV. 6. *Other Submission Requirements* of this notice.

We do not consider an application that does not comply with the deadline requirements.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact the person listed under *For Further Information Contact* of Section VII of this notice. If the Department provides an accommodation or auxiliary aid to an individual with a disability in connection with the application process, the individual's application remains subject to all other requirements and limitations in this notice.

Deadline for Intergovernmental Review: February 4, 2010.

4. *Intergovernmental Review:* This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this program.

5. *Funding Restrictions:* We specify unallowable costs in 34 CFR 646.31. We reference additional regulations outlining restrictions in the *Applicable Regulations* section of this notice.

6. *Other Submission Requirements:* Applications for grants under this program must be submitted electronically unless you qualify for an exception to this requirement in accordance with the instructions in this section.

a. *Electronic Submission of Applications.*

Applications for grants under the Student Support Services Program—CFDA Number 84.042A must be submitted electronically using e-Application, accessible through the Department's e-Grants Web site at: <http://e-grants.ed.gov>.

We will reject your application if you submit it in paper format unless, as described elsewhere in this section, you qualify for one of the exceptions to the electronic submission requirement and submit, no later than two weeks before the application deadline date, a written statement to the Department that you qualify for one of these exceptions. Further information regarding calculation of the date that is two weeks before the application deadline date is provided later in this section under *Exception to Electronic Submission Requirement*.

While completing your electronic application, you will be entering data online that will be saved into a database. You may not e-mail an electronic copy of a grant application to us.

Please note the following:

- You must complete the electronic submission of your grant application by 4:30:00 p.m., Washington, DC time, on the application deadline date. E-Application will not accept an application for this program [competition] after 4:30:00 p.m., Washington, DC time, on the application deadline date. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the application process.

- The hours of operation of the e-Grants Web site are 6:00 a.m. Monday until 7:00 p.m. Wednesday; and 6:00 a.m. Thursday until 8:00 p.m. Sunday,

Washington, DC time. Please note that, because of maintenance, the system is unavailable between 8:00 p.m. on Sundays and 6:00 a.m. on Mondays, and between 7:00 p.m. on Wednesdays and 6:00 a.m. on Thursdays, Washington, DC time. Any modifications to these hours are posted on the e-Grants Web site.

- You will not receive additional point value because you submit your application in electronic format, nor will we penalize you if you qualify for an exception to the electronic submission requirement, as described elsewhere in this section, and submit your application in paper format.

- You must submit all documents electronically, including all information you typically provide on the following forms: the Application for Federal Assistance (SF 424), the Department of Education Supplemental Information for SF 424, Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications. You must attach any narrative sections of your application as files in a .DOC (document), .RTF (rich text), or .PDF (Portable Document) format. If you upload a file type other than the three file types specified in this paragraph or submit a password protected file, we will not review that material.

- Your electronic application must comply with any page limit requirements described in this notice.

- Prior to submitting your electronic application, you may wish to print a copy of it for your records.

- After you electronically submit your application, you will receive an automatic acknowledgment that will include a PR/Award number (an identifying number unique to your application).

- Within three working days after submitting your electronic application, fax a signed copy of the SF 424 to the Application Control Center after following these steps:

- Print SF 424 from e-Application.

- The applicant's Authorizing

Representative must sign this form.

- Place the PR/Award number in the upper right hand corner of the hard-copy signature page of the SF 424.

- Fax the signed SF 424 to the Application Control Center at (202) 245-6272.

- We may request that you provide us original signatures on other forms at a later date.

Application Deadline Date Extension in Case of e-Application Unavailability:

If you are prevented from electronically submitting your application on the application deadline date because e-Application is unavailable, we will

grant you an extension of one business day to enable you to transmit your application electronically, by mail, or by hand delivery. We will grant this extension if—

- You are a registered user of e-Application and you have initiated an electronic application for this competition; and

- (a) E-Application is unavailable for 60 minutes or more between the hours of 8:30 a.m. and 3:30 p.m., Washington, DC time, on the application deadline date; or

- (b) E-Application is unavailable for any period of time between 3:30 p.m. and 4:30:00 p.m., Washington, DC time, on the application deadline date.

We must acknowledge and confirm these periods of unavailability before granting you an extension. To request this extension or to confirm our acknowledgment of any system unavailability, you may contact either (1) the person listed elsewhere in this notice under *For Further Information Contact* (see VII. Agency Contact) or (2) the e-Grants help desk at 1-888-336-8930. If e-Application is unavailable due to technical problems with the system and, therefore, the application deadline is extended, an e-mail will be sent to all registered users who have initiated an e-Application. Extensions referred to in this section apply only to the unavailability of e-Application.

Exception to Electronic Submission Requirement: You qualify for an exception to the electronic submission requirement and may submit your application in paper format if you are unable to submit an application through e-Application because—

- You do not have access to the Internet; or

- You do not have the capacity to upload large documents to e-Application; and

- No later than two weeks before the application deadline date (14 calendar days; or, if the fourteenth calendar day before the application deadline date falls on a Federal holiday, the next business day following the Federal holiday), you mail or fax a written statement to the Department, explaining which of the two grounds for an exception prevents you from using the Internet to submit your application. If you mail your written statement to the Department, it must be postmarked no later than two weeks before the application deadline date. If you fax your written statement to the Department, we must receive the faxed statement no later than two weeks before the application deadline date.

Address and mail or fax your statement to: Eileen S. Bland, U.S. Department of Education, 1990 K Street, NW., Room 7000, Washington, DC 20006-8510. Fax: (202) 502-7857.

Your paper application must be submitted in accordance with the mail or hand delivery instructions described in this notice.

b. Submission of Paper Applications by Mail.

If you qualify for an exception to the electronic submission requirement, you may mail (through the U.S. Postal Service or a commercial carrier) your application to the Department. You must mail the original and two copies of your application, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.042A) LBJ Basement Level 1, 400 Maryland Avenue, SW., Washington, DC 20202-4260.

You must show proof of mailing consisting of one of the following:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If you mail your application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

(1) A private metered postmark.

(2) A mail receipt that is not dated by the U.S. Postal Service.

If your application is postmarked after the application deadline date, we will not consider your application.

Note: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

c. Submission of Paper Applications by Hand Delivery.

If you qualify for an exception to the electronic submission requirement, you (or a courier service) may deliver your paper application to the Department by hand. You must deliver the original and two copies of your application, by hand, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.042A) 550 12th Street, SW., Room 7041, Potomac Center Plaza, Washington, DC 20202-4260. The Application Control Center accepts hand deliveries daily between 8:00 a.m.

and 4:30:00 p.m., Washington, DC time, except Saturdays, Sundays, and Federal holidays.

Note for Mail or Hand Delivery of Paper Applications: If you mail or hand deliver your application to the Department—

(1) You must indicate on the envelope and—if not provided by the Department—in Item 11 of the SF 424 the CFDA number, including suffix letter, if any, of the competition under which you are submitting your application; and

(2) The Application Control Center will mail to you a notification of receipt of your grant application. If you do not receive this grant notification within 15 business days from the application deadline date, you should call the U.S. Department of Education Application Control Center at (202) 245-6288.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this program competition are in 34 CFR 646.21 and are listed in the application package.

Note: Under the “Objectives” selection criterion, 34 CFR 646.21 (b), worth eight (8) points, applicants should address the standardized objectives in 34 CFR 646.21(a)(3) related to the participants’ academic achievements, including retention, grade point average, graduation, and transfer. Applicants also should note that the graduation objective should be measured by cohorts of students who become SSS Program participants in each year of the project and should be compared to a relevant and valid comparison group. The graduation, certificate, and transfer rates for two-year institutions should be measured over a four-year period and that of four-year institutions should be measured over a six-year period.

2. *Review and Selection Process:* A panel of non-Federal readers will review each application in accordance with the selection criteria, pursuant to 34 CFR 646.21. The individual scores of the readers will be added and the sum divided by the number of readers to determine the reader score received in the review process. In accordance with 34 CFR 646.22, the Secretary will award prior experience points to applicants that have conducted an SSS Program project within the last three fiscal years, based on their documented experience. Prior experience points, if any, will be added to the application’s averaged reader score to determine the total score for each application. If there are insufficient funds for all applications with the same total scores, the Secretary will choose among the tied applications so as to serve geographical areas that have been underserved by the SSS Program.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN). We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Reporting:* At the end of your project period, you must submit a final performance report, including financial information, as directed by the

Secretary. If you receive a multi-year award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to <http://www.ed.gov/fund/grant/apply/appforms/appforms.html>.

4. *Performance Measures:* The success of the SSS Program will be measured by the rates of SSS Program participants persisting in and completing postsecondary education at the grantee institution. All SSS Program grantees will be required to submit an annual performance report documenting the persistence and degree attainment of their participants. Since students may take different lengths of time to complete their degrees, multiple years of performance report data are needed to determine the degree completion rates of SSS Program participants. The Department of Education will aggregate the data provided in the annual performance reports from all grantees to determine the accomplishment level.

VII. Agency Contacts

For Further Information Contact: Deborah Walsh or, if unavailable, contact Lavelle Redmond, U.S. Department of Education, 1990 K Street, NW., Room 7000, Washington, DC 20006-8510. Telephone: (202) 502-7600 or by e-mail: TRIO@ed.gov.

If you use a TDD, call the FRS, toll free, at 1-800-877-8339.

VIII. Other Information

Accessible Format: Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (e.g., braille, large print, audiotape, or computer diskette) on request to the program contact person listed under *For Further Information Contact* in Section VII of this notice.

Electronic Access to This Document: You can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following site: <http://www.ed.gov/news/fedregister>.

To use PDF, you must have Adobe Acrobat Reader, which is available free at this site. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1-888-293-6498; or in the Washington, DC area at (202) 512-1530.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: <http://www.gpoaccess.gov/nara/index.html>.

Delegation of Authority: The Secretary of Education has delegated authority to Daniel T. Madzellan, Director, Forecasting and Policy Analysis for the Office of Postsecondary Education, to perform the functions and duties of the Assistant Secretary for Postsecondary Education.

Dated: October 16, 2009.

Daniel T. Madzellan,

Director, Forecasting and Policy Analysis.

[FR Doc. E9-25389 Filed 10-21-09; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF ENERGY

[OE Docket No. EA-64-A]

Application To Export Electric Energy; Basin Electric Power Cooperative

AGENCY: Office of Electricity Delivery and Energy Reliability, DOE.

ACTION: Notice of application.

SUMMARY: Basin Electric Power Cooperative (Basin Electric) has applied to amend its authorization to export electric energy from the United States to Canada issued pursuant to section 202(e) of the Federal Power Act.

DATES: Comments, protests, or requests to intervene must be submitted on or before November 23, 2009.

ADDRESSES: Comments, protests, or requests to intervene should be addressed as follows: Office of Electricity Delivery and Energy Reliability, Mail Code: OE-20, U.S. Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585-0350 (FAX 202-586-8008).

FOR FURTHER INFORMATION CONTACT: Ellen Russell (Program Office) 202-586-9624 or Michael Skinker (Program Attorney) 202-586-2793.

SUPPLEMENTARY INFORMATION: Exports of electricity from the United States to a foreign country are regulated by the Department of Energy (DOE) pursuant to sections 301(b) and 402(f) of the Department of Energy Organization Act (42 U.S.C. 7151(b), 7172(f)) and require authorization under section 202(e) of the FPA (16 U.S.C. 824a(e)).

On March 6, 1980, DOE issued Order No. EA-64 authorizing Basin Electric to transmit electric energy from the United States to Saskatchewan Power Corporation (SaskPower), the provincial electric utility of Saskatchewan, Canada, using Basin Electric's international transmission facilities known as the Tioga-Saskatchewan 230-kV intertie. Construction of these facilities was authorized by DOE in Presidential Permit No. PP-64. Order No. EA-64 contained limits on the capacity and energy that could be exported during peak and non-peak times in accordance with the 1978 Interconnection and Transaction Agreement between Basin Electric and SaskPower. For peaking exports, Basin Electric was limited to a capacity of 100 megawatts with an energy limit of 438,000 megawatt hours (MWH) in any calendar year.

On October 13, 2009, Basin Electric applied to DOE to amend Order No. EA-64 in order to be able to export to NorthPoint Energy Solutions, a subsidiary of SaskPower, and future purchasers inside Canada. In addition, Basin Electric seeks to remove the 438,000-MWH energy limit and increase the capacity limit to 165 MW, which Basin Electric claims is the present total transfer capacity of the Tioga-Saskatchewan 230-kV intertie.

The electric energy which Basin Electric proposes to export to Canada would be provided from its own generation resources or purchased by Basin Electric from other sources.

Procedural Matters: Any person desiring to become a party to these proceedings or to be heard by filing comments or protests to this application

should file a petition to intervene, comment, or protest at the address provided above in accordance with §§ 385.211 or 385.214 of the Federal Energy Regulatory Commission's Rules of Practice and Procedures (18 CFR 385.211, 385.214). Fifteen copies of each petition and protest should be filed with DOE on or before the date listed above.

Comments on the Basin Electric application to export electric energy to Canada should be clearly marked with Docket No. EA-64-A. Additional copies are to be filed directly with Dave Rantz, Basin Electric Power Cooperative, 1717 Interstate Avenue, Bismarck, ND 58503. A final decision will be made on this application after the environmental impacts have been evaluated pursuant to the National Environmental Policy Act of 1969, and a determination is made by DOE that the proposed action will not adversely impact on the reliability of the U.S. electric power supply system.

Copies of this application will be made available, upon request, for public inspection and copying at the address provided above, by accessing the program Web site at http://www.oe.energy.gov/permits_pending.htm, or by e-mailing Odessa Hopkins at Odessa.hopkins@hq.doe.gov.

Issued in Washington, DC, on October 16, 2009.

Ellen Russell,

Acting Director, Permitting and Siting, Office of Electricity Delivery and Energy Reliability.

[FR Doc. E9-25437 Filed 10-21-09; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY

[OE Docket No. EA-284-B]

Application to Export Electric Energy; Sempra Energy Solutions LLC

AGENCY: Office of Electricity Delivery and Energy Reliability, DOE.

ACTION: Notice of application.

SUMMARY: Sempra Energy Solutions LLC (SES) applied to renew its authority to export electric energy from the United States to Mexico for a period of five years pursuant to section 202(e) of the Federal Power Act.

DATES: Comments, protests, or requests to intervene must be submitted on or before November 23, 2009.

ADDRESSES: Comments, protests, or requests to intervene should be addressed as follows: Office of Electricity Delivery and Energy Reliability, Mail Code: OE-20, U.S. Department of Energy, 1000

Independence Avenue, SW., Washington, DC 20585-0350 (FAX 202-586-8008).

FOR FURTHER INFORMATION CONTACT: Ellen Russell (Program Office) 202-586-9624 or Michael Skinker (Program Attorney) 202-586-2793.

SUPPLEMENTARY INFORMATION: Exports of electricity from the United States to a foreign country are regulated by the Department of Energy (DOE) pursuant to sections 301(b) and 402(f) of the Department of Energy Organization Act (42 U.S.C. 7151(b), 7172(f)) and require authorization under section 202(e) of the FPA (16 U.S.C. 824a(e)).

On September 4, 2003, DOE issued Order No. EA-284 authorizing Sempra Energy Solutions LLC (SES) to transmit electric energy from the United States to Mexico as a power marketer for a term of three-years. On March 12, 2007, DOE issued Order No. EA-284-A, which renewed that authority for an additional three-year term. That authority will expire on March 12, 2010. On September 30, 2009, DOE received an application from SES, as later amended on October 6, 2009, to renew its authority to export electric energy to Mexico for a five-year term.

The electric energy which SES proposes to export to Mexico would be surplus energy purchased from electric utilities, Federal power marketing agencies and other entities. The energy SES purchases will be delivered to Mexico over transmission facilities owned by San Diego Gas and Electric Company (SDG&E). The construction, operation, maintenance and connection of these facilities was previously authorized by a Presidential permit issued pursuant to Executive Order 10485, as amended.

Procedural Matters: Any person desiring to become a party to these proceedings or to be heard by filing comments or protests to this application should file a petition to intervene, comment, or protest at the address provided above in accordance with §§ 385.211 or 385.214 of the Federal Energy Regulatory Commission's Rules of Practice and Procedures (18 CFR 385.211, 385.214). Fifteen copies of each petition and protest should be filed with DOE on or before the date listed above.

Comments on the SES application to export electric energy to Mexico should be clearly marked with Docket No. EA-284-B. Additional copies are to be filed directly with Greg Bass, Sempra Energy Solutions LLC, 401 West A Street, Suite 500, San Diego, CA 92101. A final decision will be made on this application after the environmental impacts have been evaluated pursuant

to the National Environmental Policy Act of 1969, and a determination is made by DOE that the proposed action will not adversely impact on the reliability of the U.S. electric power supply system.

Copies of this application will be made available, upon request, for public inspection and copying at the address provided above, by accessing the program Web site at http://www.oe.energy.gov/permits_pending.htm, or by e-mailing Odessa Hopkins at Odessa.hopkins@hq.doe.gov.

Issued in Washington, DC, on October 16, 2009.

Anthony J. Como,

Director, Permitting and Siting, Office of Electricity Delivery and Energy Reliability.

[FR Doc. E9-25438 Filed 10-21-09; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Hanford

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Hanford. The Federal Advisory Committee Act (Pub. L. 92-463, 86 Stat. 770) requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Thursday, November 5, 2009, 9 a.m.-5 p.m. Friday, November 6, 2009, 8:30 a.m.-4 p.m.

ADDRESSES: Shilo Inn, 50 Comstock Street, Richland, Washington 99352, Phone: (509) 946-4661 or (800) 222-2244, Fax: (509) 943-6741.

FOR FURTHER INFORMATION CONTACT:

Paula Call, Federal Coordinator, Department of Energy Richland Operations Office, 825 Jadwin Avenue, P.O. Box 550, A7-75, Richland, WA 99352; Phone: (509) 376-2048; or E-mail: Paula_K_Call@rl.gov.

SUPPLEMENTARY INFORMATION: *Purpose of the Board:* The purpose of the Board is to make recommendations to DOE in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda:

- Agency Updates (Department of Energy Office of River Protection and Richland Operations Office; Washington State Department of Ecology; U.S. Environmental Protection Agency); American Recovery and Reinvestment Act;

- Committee Updates, including: Tank Waste Committee; River and Plateau Committee; Health, Safety and Environmental Protection Committee; Public Involvement Committee; and Budgets and Contracts Committee;

- Central Plateau Strategy Work Session;

- Tank Closure & Waste Management Environmental Impact Statement Overview;

- Draft advice on the Tri-Party Agreement (TPA) Community Relations Plan;

- Draft advice on the Hanford Cleanup Completion Framework;

- Draft advice on the Proposed Consent Decree and TPA modifications;

- NEPA/CERCLA/RCRA Tutorial;

- Board Business.

Public Participation: The meeting is open to the public. The EM SSAB, Hanford, 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 Paula Call at least seven days in advance of the meeting at the phone number listed above. Written statements may be filed with the Board either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact Paula Call at the address or telephone number listed above. Requests must be received five days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make public comment will be provided a maximum of five minutes to present their comments. This notice is being published less than 15 days prior to the meeting date due to programmatic issues that had to be resolved prior to the meeting date.

Minutes: Minutes will be available by writing or calling Paula Call's office at the address or phone number listed above. Minutes will also be available at the following Web site: <http://www.hanford.gov/?page=413&parent=397>.

Issued at Washington, DC on October 16, 2009.

Rachel Samuel,

Deputy Committee Management Officer.

[FR Doc. E9-25433 Filed 10-21-09; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission**

[Docket No. CP10-6-000]

Perryville Gas Storage LLC; Notice of Application

October 15, 2009.

Take notice that on October 14, 2009, Perryville Gas Storage LLC (Perryville), Three Riverway, Suite 400, Houston, TX 77056, filed in Docket No. CP10-6-000, a petition for Exemption of Temporary Acts and Operations from Certificate Requirements, pursuant to Rule 207(a)(5) of the Commission's Rules of Practice and Procedure, and section 7(c)(1)(B) of the Natural Gas Act (NGA), to perform specific temporary activity related to drill site preparation and the drilling of one salt water disposal test well in Franklin Parish, Louisiana, all as more fully set forth in the application which is on file with the Commission and open to public inspection. This filing may also be viewed on the Commission's Web site at <http://www.ferc.gov> using the "eLibrary" link. Enter the docket number, excluding the last three digits, in the docket number field to access the document. For assistance, call (202) 502-8659 or TTY, (202) 208-3676.

Any questions regarding this application should be directed to J. Gordon Pennington, Attorney at Law, 2707 N. Kensington St., Arlington, Virginia 22207, at (703) 533-7638.

Pursuant to Section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify Federal and State agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all Federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party

to the proceedings for this project should, on or before the comment date stated below, file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 14 copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commentors will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commentors will not be required to serve copies of filed documents on all other parties. However, the non-party commentors will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the "eFiling" link at <http://www.ferc.gov>. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy

Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at <http://www.ferc.gov>, using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail FERCOnlineSupport@ferc.gov, or call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Comment Date: October 22, 2009.

Kimberly D. Bose,

Secretary.

[FR Doc. E9-25399 Filed 10-21-09; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission**

[Docket No. CP09-433-000]

Fayetteville Express Pipeline LLC; Notice of Availability of the Environmental Assessment for the Proposed Fayetteville Express Pipeline Project

October 15, 2009.

The staff of the Federal Energy Regulatory Commission (FERC or Commission) has prepared an environmental assessment (EA) of the Fayetteville Express Pipeline Project proposed by Fayetteville Express Pipeline LLC (FEP) in the above referenced docket. FEP requests authorization to transport natural gas from the Fayetteville Shale production area in Arkansas and provide about 2,000,000 dekatherms per day of new transportation capacity to markets in the Midwest, Southeast, and Northeast.

The EA assesses the potential environmental effects of the construction and operation of the proposed Fayetteville Express Pipeline Project (Project) in accordance with the requirements of the National Environmental Policy Act. The FERC staff concludes that approval of the proposed project, with appropriate mitigating measures, would not constitute a major Federal action significantly affecting the quality of the human environment.

The Project includes the following proposed facilities:

- About 185 miles of 42-inch-diameter pipeline from Conway County, Arkansas to Panola County, Mississippi;

- A total of 71,465 horsepower at the new Russell Compressor Station in White County, Arkansas;

- 18 meter stations at various gas receipt/delivery locations; and

- Other appurtenant facilities as discussed in the EA.

The EA has been placed in the public files of the FERC. A limited number of copies of the EA are available for distribution and public inspection at: Federal Energy Regulatory Commission, Public Reference Room, 888 First Street, NE., Room 2A, Washington, DC 20426, (202) 502-8371.

Copies of the EA have been mailed to Federal, State, and local agencies; interested groups and individuals; newspapers and libraries in the project area; and parties to this proceeding.

Any person wishing to comment on the EA may do so. To ensure consideration prior to a Commission decision on the proposal, it is important that we receive your comments before the date specified below.

Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. The more specific your comments, the more useful they will be. To ensure that your comments are timely and properly recorded, please send in your comments so that they will be received in Washington, DC on or before November 16, 2009.

For your convenience, there are three methods in which you can use to submit your comments to the Commission. In all instances please reference the project docket number (CP09-433-000) with your submission. The Commission encourages electronic filing of comments and has dedicated eFiling expert staff available to assist you at 202-502-8258 or efiling@ferc.gov.

(1) You may file your comments electronically by using the *Quick Comment* feature, which is located on the Commission's Internet Web site at <http://www.ferc.gov> under the link to *Documents and Filings*. A Quick Comment is an easy method for interested persons to submit text-only comments on a project;

(2) You may file your comments electronically by using the *eFiling* feature, which is located on the Commission's Internet Web site at <http://www.ferc.gov> under the link to *Documents and Filings*. eFiling involves preparing your submission in the same manner as you would if filing on paper, and then saving the file on your computer's hard drive. You will attach that file as your submission. New eFiling users must first create an account by clicking on "Sign up" or

"eRegister." You will be asked to select the type of filing you are making. A comment on a particular project is considered a "Comment on a Filing;" or

(3) You may file your comments via mail to the Commission by sending an original and two copies of your letter to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First St., NE., Room 1A, Washington, DC 20426;

If you choose the option to mail your comments, label one copy of the comments for the attention of Gas Branch 1, PJ11.1. Please mail your comments promptly, so that they will be received in Washington, DC on or before November 16, 2009.

Comments will be considered by the Commission but will not serve to make the commentor a party to the proceeding. Any person seeking to become a party to the proceeding must file a motion to intervene pursuant to Rule 214 of the Commission's Rules of Practice and Procedures (18 Code of Federal Regulations (CFR) 385.214).¹ Only intervenors have the right to seek rehearing of the Commission's decision.

Affected landowners and parties with environmental concerns may be granted intervenor status upon showing good cause by stating that they have a clear and direct interest in this proceeding which would not be adequately represented by any other parties. You do not need intervenor status to have your comments considered.

Additional information about the project is available from the Commission's Office of External Affairs, at 1-866-208-FERC (3372) or on the FERC Internet Web site (<http://www.ferc.gov>) using the eLibrary link. Click on the eLibrary link, click on "General Search" and enter the docket number excluding the last three digits in the Docket Number field (*i.e.* CP09-433). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at FercOnlineSupport@ferc.gov or toll free at 1-866-208-3676, or for TTY, contact (202) 502-8659. The eLibrary link also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with

¹ Interventions may also be filed electronically via the Internet in lieu of paper. See the previous discussion on filing comments electronically.

notification of these filings, document summaries and direct links to the documents. Go to <http://www.ferc.gov/esubscribenow.htm>.

Kimberly D. Bose,
Secretary.

[FR Doc. E9-25401 Filed 10-21-09; 8:45 am]
BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. RP09-844-000 and RP09-844-001]

Texas Gas Transmission, LLC; Notice of Request for Permission To Withdraw Tariff Filing

October 15, 2009.

Take notice that on October 9, 2009, Texas Gas Transmission, LLC (Texas Gas) filed to request for authority from the Commission to withdraw the proposed tariff sheets filed in the above-captioned dockets, without prejudice to Texas Gas re-filing at a later time. Texas Gas contends that no party will be harmed by the Commission permitting Texas Gas to withdraw its filings as the proposed tariff changes have not yet taken effect. Texas Gas also requests the authority to file the information required by the Commission in its order accepting and suspending the tariff filings, subject to conditions¹ in upcoming certificate proceedings during the next six months.

Any person desiring to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 85.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Such protests must be filed on or before 5 p.m. Eastern time on the comment date as indicated below. Anyone filing a protest must serve a copy of that document on the parties to the proceeding.

The Commission encourages electronic submission of protests in lieu of paper, using the FERC Online links at <http://www.ferc.gov>. To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling

¹ *Texas Gas Transmission, LLC*, 128 FERC ¶ 61,220 (2009).

link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

The filing in the above proceeding is accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket. For assistance with any FERC Online service, please e-mail FERCOnlineSupport@ferc.gov or call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Comment Date: 5 p.m. Eastern Time on October 23, 2009.

Kimberly D. Bose,
Secretary.

[FR Doc. E9-25398 Filed 10-21-09; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2157-188]

Public Utility District No.1 of Snohomish County; Notice of Settlement Agreement and Soliciting Comments, Extending Due Date for Filing Motions To Intervene and Protests, Comments, Recommendations, Preliminary Terms and Conditions, and Preliminary Fishway Prescriptions, and Modifying Process Plan

October 15, 2009.

Take notice that the following Settlement Agreement (Settlement) has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Settlement Agreement.

b. *Project No.:* P-2157-188.

c. *Date Filed:* October 14, 2009.

d. *Applicant:* Public Utility District No. 1 of Snohomish County.

e. *Name of Project:* Henry M. Jackson Hydroelectric Project.

f. *Location:* The existing project is located on the Sultan River in Snohomish County, Washington, about 20 miles east of Everett, Washington. The project penstock underlies 10.9 acres of Mount Baker-Snoqualmie National Forest.

g. *Filed Pursuant to:* Rule 602 of the Commission's Rules of Practice and Procedure, 18 CFR 385.602, Federal Power Act 16 U.S.C. 791 (a)—825(r)

h. *Applicant Contact:* Public Utility District No. 1 of Snohomish County (District), Steven J. Klein, General Manager, 2320 California Street, P.O. Box 1107, Everett, WA 98206-1107.

i. *FERC Contact:* David Turner (202) 502-6091 or via e-mail at david.turner@ferc.gov.

j. *Deadline for filing comments on the Settlement:* November 6, 2009. Reply comments due December 21, 2009. All documents (original and eight copies) should be filed with: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

k. The District filed a comprehensive settlement agreement (Agreement) on behalf of itself, United States National Marine Fisheries Service, United States Forest Service, United States Fish and Wildlife Service, United States National Park Service, Washington Department of Fish and Wildlife, Washington Department of Ecology, Tulalip Tribes of Washington, Snohomish County, City of Everett, City of Sultan, and American Whitewater. The purpose of the Agreement is to resolve among the signatories all issues associated with issuance of a new license for the project, including, in part, reservoir operations, minimum instream flows, process flows, whitewater boating flows, ramping rates, fish passage, fish habitat improvements, wildlife habitat management, marbled murrelet protection measures, recreation, and historic properties management.

The District requests that the Commission: (1) Accept and incorporate, without material modification, all of the proposed license articles in Appendix 1 of the Settlement in the new project license; and (2) issue a new license for a term of 45 years.

l. The A copy of the Settlement Agreement is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at <http://www.ferc.gov>, using the "e-Library" link. Enter the docket number, excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at FERCOnlineSupport@ferc.gov or toll-free at 1-866-208-3676, or for TTY, (202) 502-8659. A copy is also available for inspection and reproduction at the address in item h above.

Register online at <http://www.ferc.gov/esubscribenow.htm> to be notified via e-mail of new filings and

issuances related to this or other pending projects. For assistance, contact FERC Online Support.

m. *Procedural Schedule:* We are extending the due date to file interventions, recommendations, preliminary terms and conditions, and fishway prescriptions and reply comments on these filings to coordinate with the filing of comments on the Settlement. Therefore, the application will be processed according to the following Hydro Licensing Schedule. Revisions to the schedule may be made as appropriate.

Milestone	Target date
Filing of Interventions, Recommendations, Preliminary Terms and Conditions, and Fishway Prescriptions.	November 6, 2009.
Reply Comments Due	December 21, 2009.
Issue Draft EA	May 5, 2010.
Comments on Draft EA Due.	June 4, 2010.
Filing of Modified Mandatory Terms and Conditions.	August 3, 2010.
Issue Final EA	November 1, 2010.

Kimberly D. Bose,
Secretary.

[FR Doc. E9-25400 Filed 10-21-09; 8:45 am]

BILLING CODE 6717-01-P

ENVIRONMENTAL PROTECTION AGENCY

[FRL-8971-7]

Science Advisory Board Staff Office Notification of a Public Teleconference of the Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) Science Advisory Board (SAB) Staff Office announces a public teleconference of the Clean Air Scientific Advisory Committee Ozone Review Panel to conduct a consultation on EPA's draft *Integrated Review Plan for the National Ambient Air Quality Standards for Ozone (External Review Draft, September 2009)*.

DATES: The public teleconference will be held on Friday, November 13, 2009 from 10 a.m. to 2 p.m. (Eastern Time).

ADDRESSES: The public teleconference will be conducted by telephone only.

FOR FURTHER INFORMATION CONTACT: Any member of the public who wants further information concerning the teleconference may contact Dr. Holly Stallworth, Designated Federal Officer (DFO), EPA Science Advisory Board (1400F), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; via telephone/voice mail (202) 343-9867; fax (202) 233-0643; or e-mail at stallworth.holly@epa.gov. General information concerning the CASAC can be found on the EPA Web site at <http://www.epa.gov/casac>.

SUPPLEMENTARY INFORMATION:

Background: The Clean Air Scientific Advisory Committee (CASAC) was established under section 109(d)(2) of the Clean Air Act (CAA or Act) (42 U.S.C. 7409) as an independent scientific advisory committee. CASAC provides advice, information and recommendations on the scientific and technical aspects of air quality criteria and national ambient air quality standards (NAAQS) under sections 108 and 109 of the Act. The CASAC is a Federal advisory committee chartered under the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C., App. The CASAC Ozone Review Panel will comply with the provisions of FACA and all appropriate SAB Staff Office procedural policies.

Section 109(d)(1) of the CAA requires that the Agency periodically review and revise, as appropriate, the air quality criteria and the National Ambient Air Quality Standards (NAAQS) for the six "criteria" air pollutants, including ozone. EPA is currently reviewing the primary (health-based) and secondary (welfare-based) NAAQS for ozone. Accordingly, the SAB Staff Office solicited nominations for the Ozone Review Panel on June 26, 2008 (73 FR 36319-36321). Membership of the Panel is listed at <http://yosemite.epa.gov/sab/sabpeople.nsf/WebExternalSubCommitteeRosters?OpenView&committee=CASAC&subcommittee=Ozone%20Review%20Panel>.

EPA is developing the *Integrated Review Plan* (IRP) that will serve as the framework for its review of the ozone NAAQS. The IRP presents background information, the schedule for the review, the process to be used in conducting the review, and the key policy-relevant science issues that will guide the review. The IRP also discusses the frameworks for the various documents to be prepared by the EPA as part of the review, including an integrated science assessment (ISA) and a risk/exposure assessment (REA), and policy assessment that will be submitted

for later CASAC review and public comment. The purpose of the November 13, 2009 teleconference is for the CASAC Panel to provide consultative advice on the draft *Integrated Review Plan for the National Ambient Air Quality Standards for Ozone*. A teleconference was previously planned for March 30, 2009 and noticed in the **Federal Register** on February 19, 2009 (74 FR 7689) but was subsequently cancelled at the request of the EPA Office of Air and Radiation (OAR).

Technical Contacts: Any questions concerning EPA's *Integrated Review Plan* for ozone should be directed to Dr. David McKee, OAR, at (919) 541-5288 or mckee.dave@epa.gov.

Availability of Meeting Materials: A meeting agenda and other materials for the meeting will be placed on the CASAC Web site at <http://yosemite.epa.gov/sab/SABPRODUCT.NSF/81e39f4c09954fcb85256ead006be86e/97662d128e20ca968525746b006ce9fd!OpenDocument>. The *Integrated Review Plan for the National Ambient Air Quality Standards for Ozone* will be available at http://www.epa.gov/ttn/naaqs/standards/ozone/s_o3_index.html (see "Planning Documents").

Procedures for Providing Public Input: Interested members of the public may submit relevant written or oral information for consideration on the topics included in this advisory activity. *Oral Statements:* To be placed on the public speaker list for the November 13, 2009 teleconference, interested parties should notify Dr. Holly Stallworth, DFO, by e-mail no later than November 9, 2009. Individuals making oral statements will be limited to three minutes per speaker. *Written Statements:* Written statements for the November 13, 2009 teleconference should be received in the SAB Staff Office by November 9, 2009 so that the information may be made available to the CASAC Panel for its consideration prior to this meeting. Written statements should be supplied to the DFO in the following formats: one hard copy with original signature and one electronic copy via e-mail (acceptable file format: Adobe Acrobat PDF, MS Word, WordPerfect, MS PowerPoint, or Rich Text files in IBM-PC/Windows 98/2000/XP format). Submitters are asked to provide versions of each document submitted with and without signatures, because the SAB Staff Office does not publish documents with signatures on its Web sites.

Accessibility: For information on access or services for individuals with disabilities, please contact Dr. Stallworth at the phone number or e-mail address noted above, preferably at

least ten days prior to the teleconference, to give EPA as much time as possible to process your request.

Dated: October 15, 2009.

Anthony F. Maciorowski,
Deputy Director, EPA Science Advisory Board Staff Office.

[FR Doc. E9-25465 Filed 10-21-09; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[FRL-8971-8]

EPA Science Advisory Board Staff Office Request for Nominations of Experts for the SAB Trichloroethylene (TCE) Review Panel

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice request for nominations.

SUMMARY: The Science Advisory Board (SAB) Staff Office is requesting public nominations of experts to form an SAB *Ad Hoc* Panel to review EPA's health effects assessment for Trichloroethylene (TCE).

DATES: Nominations should be submitted by November 12, 2009 per instructions below.

FOR FURTHER INFORMATION CONTACT: Any member of the public wishing further information regarding this Request for Nominations may contact Dr. Marc Rigas, Designated Federal Officer (DFO), SAB Staff Office, by telephone/voice mail at (202) 343-9978; by fax at (202) 233-0643; or via e-mail at rigas.marc@epa.gov. General information concerning the EPA Science Advisory Board can be found on the EPA SAB Web site at <http://www.epa.gov/sab>.

SUPPLEMENTARY INFORMATION:

Background: EPA's Integrated Risk Information System (IRIS) is an electronic database containing descriptive and quantitative toxicological information on human health effects that may result from chronic exposure to various substances in the environment. This information supports human health risk assessments, and includes hazard identification and dose-response data and derivations of oral reference doses (RfDs) and inhalation reference concentrations (RfCs) for noncancer effects and oral slope factors and oral and inhalation unit risks for cancer effects. IRIS is prepared and maintained by EPA's National Center for Environmental Assessment (NCEA) within the Office of Research and Development (ORD). ORD has

developed a draft IRIS Toxicological Assessment for TCE and has requested that the SAB conduct a review of its draft Assessment.

In 2001, ORD developed a draft IRIS Toxicological Assessment for TCE, which was released for public comment and external peer review. In 2002, the Environmental Health Committee of the SAB reviewed the draft TCE Assessment and made several recommendations to strengthen the dose-response assessment. In 2004, in preparation for development of a new TCE assessment, the National Research Council (NRC) was requested to provide a scientific consultation on key scientific issues related to assessing the human health risks of TCE, including those relevant to hazard characterization/mode of action, physiologically-based pharmacokinetic (PBPK) modeling, and dose-response assessment. ORD has taken the recommendations and conclusions included in the NRC's report, which was released in 2006, into account as it developed a new revised draft IRIS Toxicological Assessment for TCE. ORD has requested that the SAB conduct a review of its revised draft Assessment.

The SAB was established by 42 U.S.C. 4365 to provide independent scientific and technical advice, consultation and recommendations to the EPA Administrator on the technical basis for Agency positions and regulations. The SAB Staff Office will form an expert Panel to review ORD's draft IRIS Toxicological Assessment for TCE. The SAB Panel will comply with the provisions of the Federal Advisory Committee Act (FACA) and all appropriate SAB procedural policies. Upon completion, the Panel's report will be submitted to the chartered SAB for final approval for transmittal to the EPA Administrator. The TCE Review Panel is being asked to comment on the scientific soundness of the Agency's draft IRIS review.

Availability of the Review Materials: The EPA draft IRIS Toxicological Review document to be reviewed by the TCE Review Panel will be made available by ORD at the following URL <http://epa.gov/ncea> (under "Recent Additions"). For questions concerning the review materials, please contact Dr. Weihsueh Chiu, at (703) 347-8607, or chiu.weihsueh@epa.gov.

Request for Nominations: The SAB Staff Office is requesting nominations of nationally recognized experts with expertise in one or more of the following areas, particularly with respect to TCE and its metabolites: toxicokinetics; toxicology; carcinogenic modes of action; physiologically-based pharmacokinetic (PBPK) modeling;

epidemiology; statistics; dose-response modeling; and risk assessment.

Process and Deadline for Submitting Nominations: Any interested person or organization may nominate qualified individuals for possible service on the TCE Review Panel in the areas of expertise described above. Nominations should be submitted in electronic format (which is preferred over hard copy) following the instructions for "Nominating Experts to Advisory Panels and Ad Hoc Committees Being Formed" provided on the SAB Web site. The instructions can be accessed through the "Nomination of Experts" link on the blue navigational bar on the SAB Web site at <http://www.epa.gov/sab>. To receive full consideration, nominations should include all of the information requested.

EPA's SAB Staff Office requests: contact information about the person making the nomination; contact information about the nominee; the disciplinary and specific areas of expertise of the nominee; the nominee's curriculum vita; sources of recent grants and/or contracts; and a biographical sketch of the nominee indicating current position, educational background, research activities, and recent service on other national advisory committees or national professional organizations.

Persons having questions about the nomination procedures, or who are unable to submit nominations through the SAB Web site, should contact Dr. Marc Rigas, DFO, as indicated above in this notice. Nominations should be submitted in time to arrive no later than November 12, 2009. EPA values and welcomes diversity. In an effort to obtain nominations of diverse candidates, EPA encourages nominations of women and men of all racial and ethnic groups.

The EPA SAB Staff Office will acknowledge receipt of nominations. The names and biosketches of qualified nominees identified by respondents to the **Federal Register** notice and additional experts identified by the SAB Staff will be posted on the SAB Web site at <http://www.epa.gov/sab>. Public comments on this "Short List" of candidates will be accepted for 21 calendar days. The public will be requested to provide relevant information or other documentation on nominees that the SAB Staff Office should consider in evaluating candidates.

For the EPA SAB Staff Office, a balanced subcommittee or review panel includes candidates who possess the necessary domains of knowledge, the relevant scientific perspectives (which, among other factors, can be influenced

by work history and affiliation), and the collective breadth of experience to adequately address the charge. In establishing the TCE Review Panel, the SAB Staff Office will consider public comments on the "Short List" of candidates, information provided by the candidates themselves, and background information independently gathered by the SAB Staff Office. Selection criteria to be used for Panel membership include: (a) Scientific and/or technical expertise, knowledge, and experience (primary factors); (b) availability and willingness to serve; (c) absence of financial conflicts of interest; (d) absence of an appearance of a lack of impartiality; and (e) skills working in committees, subcommittees and advisory panels; and, for the Panel as a whole, (f) diversity of, and balance among scientific expertise and viewpoints.

The SAB Staff Office's evaluation of an absence of financial conflicts of interest will include a review of the "Confidential Financial Disclosure Form for Special Government Employees Serving on Federal Advisory Committees at the U.S. Environmental Protection Agency" (EPA Form 3110-48). This confidential form allows Government officials to determine whether there is a statutory conflict between that person's public responsibilities (which includes membership on an EPA Federal advisory committee) and private interests and activities, or the appearance of a lack of impartiality, as defined by Federal regulation. The form may be viewed and downloaded from the following URL address <http://www.epa.gov/sab/pdf/epaform3110-48.pdf>.

The approved policy under which the EPA SAB Office selects subcommittees and review panels is described in the following document: *Overview of the Panel Formation Process at the Environmental Protection Agency Science Advisory Board* (EPA-SAB-EC-02-010), which is posted on the SAB Web site at <http://www.epa.gov/sab/pdf/ec02010.pdf>.

Dated: October 15, 2009.

Anthony F. Maciorowski,
Deputy Director, EPA Science Advisory Board Staff Office.

[FR Doc. E9-25457 Filed 10-21-09; 8:45 am]

BILLING CODE 6560-50-P

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION**Public Town Hall Listening Sessions on EEOC's Proposed Regulations Under the ADA Amendments Act of 2008**

AGENCY: Equal Employment Opportunity Commission.

ACTION: Notice of Town Hall Listening Sessions.

SUMMARY: The U.S. Equal Employment Opportunity Commission (EEOC) and the U.S. Department of Justice (DOJ) Civil Rights Division will hold a series of joint Town Hall Listening Sessions on EEOC's proposed regulations under the ADA Amendments Act of 2008 (ADAAA), 74 FR 48431 (09/23/2009). These joint sessions will be held throughout the country to obtain direct input from the business/employer communities and the disability and disability advocacy communities on the proposed regulations.

DATES: The Town Hall Listening Sessions will be held on October 26, 2009 in Oakland, CA; October 30, 2009 in Philadelphia, PA; November 17, 2009 in Chicago, IL; and, November 20, 2009 in New Orleans, LA. Each session will be from 9 a.m. until 4 p.m. Specific information on each session appears below.

ADDRESSES: The locations of the sessions are:

1. Oakland, CA—California Endowment, 1111 Broadway, 7th Floor, Oakland, CA 94607.
2. Philadelphia, PA—Liberty Resources, 714 Market Street, Suite 100, Philadelphia, PA 19106.
3. Chicago, IL—Access Living, 115 West Chicago Avenue, Chicago, IL 60654.
4. New Orleans, LA—University of New Orleans Training Resource and Assistive-Technology Center (UNO-TRAC), 2000 Lakeshore Drive, New Orleans, LA 70148.

FOR FURTHER INFORMATION OR TO REGISTER AS A SPEAKER CONTACT:

1. Oakland, CA—Ms. Linda Li at 415-625-5618 (TTY 415-625-5610) or at Linda.Li@eeoc.gov.
2. Philadelphia, PA—Ms. Mary Tiernan at 215-440-2671 (TTY 215-440-2610) or at Mary.Tiernan@eeoc.gov.
3. Chicago, IL—Ms. Rita Coffey at 312-353-7254 (TTY 312-353-2421) or at Rita.Coffey@eeoc.gov.
4. New Orleans, LA—Ms. Maple Thomas at 504-595-2827 (TTY 504-595-2958) or at Maple.Thomas@eeoc.gov.

SUPPLEMENTARY INFORMATION: The sessions will be presided over by

EEOC's Acting Chairman, Stuart J. Ishimaru, Acting Vice Chair Christine Griffin, and Commissioner Constance S. Barker, as well as by DOJ's Deputy Assistant Attorney General for Civil Rights, Samuel Bagenstos, Counsel to the Assistant Attorney General for Civil Rights, Mazen Baswari, and Chief of the Disability Rights Section of the Civil Rights Division, John Wodatch.

The Town Hall Listening Sessions provide an opportunity for these officials to hear directly from stakeholders of all perspectives on the proposed regulations. Individuals representing themselves or organizations are urged to take advantage of this opportunity to provide input on the EEOC's Notice of Proposed Rulemaking which can be viewed, along with a question-and-answer guide, at <http://www.eeoc.gov>.

Five-minute time slots to address the panel will be available from 9 a.m. to 4 p.m. Some of the slots will be available on an advance registration basis and some on a first-come, first-served, sign-up basis at the event. Members of the public are also invited to attend and view the proceedings, with space available on a first-come, first-served basis. Written comments may be submitted at the sessions.

Both EEOC and DOJ want to encourage all individuals and organizations who cannot attend these events to submit input in writing. The public may submit comments and attachments electronically at <http://www.regulations.gov>, which is the Federal eRulemaking Portal. The ID # is 3046-AA85. Written comments may also be submitted to Stephen Llewellyn, Executive Officer, Executive Secretariat, Equal Employment Opportunity Commission, 131 M Street, NE., Suite 4NW08R, Room 6NE03F, Washington, DC 20507. The Commission will accept comments transmitted by facsimile ("FAX") machine. The telephone number of the FAX receiver is (202) 663-4114. (This is not a toll-free number.) Only comments of six or fewer pages will be accepted via FAX transmittal. Comments must be submitted on or before November 23, 2009.

Sign Language Interpreters, CART, and assistive listening devices will be available. If you need printed materials in an alternative format e-mail Elisa.gonzalez.ctr@tma.osd.mil Please advise as to your needs and the location (city) of the event you will be attending. In addition as reasonable accommodation, there will be limited availability to provide public input by telephone. To request this

accommodation you must register in advance.

Dated: October 19, 2009.

Stuart J. Ishimaru,
Acting Chairman.

[FR Doc. E9-25458 Filed 10-21-09; 8:45 am]

BILLING CODE 6570-10-P

FEDERAL DEPOSIT INSURANCE CORPORATION**Notice of Agency Meeting**

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that at 10:12 a.m. on Tuesday, October 20, 2009, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session to consider matters related to the Corporation's supervision and resolution activities.

In calling the meeting, the Board determined, on motion of Director John E. Bowman (Acting Director, Office of Thrift Supervision), seconded by Vice Chairman Martin J. Gruenberg, concurred in by Director Thomas J. Curry (Appointive), Director John C. Dugan (Comptroller of the Currency), and Chairman Sheila C. Bair, that Corporation business required its consideration of the matters which were to be the subject of this meeting on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), and (c)(9)(B) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), and (c)(9)(B)).

The meeting was held in the Board Room of the FDIC Building located at 550-17th Street, NW., Washington, DC.

Dated: October 20, 2009.

Federal Deposit Insurance Corporation.

Robert E. Feldman,
Executive Secretary.

[FR Doc. E9-25556 Filed 10-20-09; 4:15 pm]

BILLING CODE P

FEDERAL RESERVE SYSTEM**Federal Open Market Committee; Domestic Policy Directive of September 22 and 23, 2009**

In accordance with § 271.25 of its rules regarding availability of information (12 CFR part 271), there is set forth below the domestic policy

directive issued by the Federal Open Market Committee at its meeting held on September 22 and 23, 2009.¹

The Federal Open Market Committee seeks monetary and financial conditions that will foster price stability and promote sustainable growth in output. To further its long-run objectives, the Committee seeks conditions in reserve markets consistent with federal funds trading in a range from 0 to ¼ percent. The Committee directs the Desk to purchase agency debt, agency MBS, and longer-term Treasury securities during the intermeeting period with the aim of providing support to private credit markets and economic activity. The timing and pace of these purchases should depend on conditions in the markets for such securities and on a broader assessment of private credit market conditions. The Desk is expected to complete purchases of about \$300 billion of longer-term Treasury securities by the end of October. It is also expected to execute purchases of up to \$200 billion in housing-related agency debt and about \$1.25 trillion of agency MBS by the end of the first quarter of 2010. The Desk is expected to gradually slow the pace of these purchases as they near completion. The Committee anticipates that outright purchases of securities will cause the size of the Federal Reserve's balance sheet to expand significantly in coming months. The System Open Market Account Manager and the Secretary will keep the Committee informed of ongoing developments regarding the System's balance sheet that could affect the attainment over time of the Committee's objectives of maximum employment and price stability.

By order of the Federal Open Market Committee, October 15, 2009.

Brian F. Madigan,

Secretary, Federal Open Market Committee.

[FR Doc. E9-25425 Filed 10-21-09; 8:45 am]

BILLING CODE 6210-01-S

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at www.ffiec.gov/nic/.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than November 16, 2009.

A. Federal Reserve Bank of Kansas City (Todd Offenbacher, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198-0001:

1. *Stockmens Financial Corporation*, Rapid City, South Dakota; to acquire 100 percent of the voting shares of *Valentine Bancorporation*, and thereby indirectly acquire voting shares of *First National Bank of Valentine*, both of Valentine, Nebraska.

Board of Governors of the Federal Reserve System, October 19, 2009.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. E9-25448 Filed 10-21-09; 8:45 am]

BILLING CODE 6210-01-S

FEDERAL TRADE COMMISSION

Granting of Request for Early Termination of the Waiting Period Under the Premerger Notification Rules

Section 7A of the Clayton Act, 15 U.S.C. 18a, as added by Title II of the Hart-Scott Rodino Antitrust Improvements Act of 1976, requires persons contemplating certain mergers or acquisitions to give the Federal Trade Commission and the Assistant Attorney General advance notice and to wait designated periods before consummation of such plans. Section 7A(b)(2) of the Act permits the agencies, in individual cases, to terminate this waiting period prior to its expiration and requires that notice of this action be published in the **Federal Register**.

The following transactions were granted early termination of the waiting period provided by law and the premerger notification rules. The grants were made by the Federal Trade Commission and the Assistant Attorney General for the Antitrust Division of the Department of Justice. Neither agency intends to take any action with respect to these proposed acquisitions during the applicable waiting period.

TRANSACTION GRANTED EARLY TERMINATION

ET date	Trans No.	ET req status	Party name
08-SEP-09	20090701	G	Clayton, Dubifler & Rice Fund VIII, L.P. NCI Building Systems, Inc. NCI Building Systems, Inc.
		G	
		G	
09-SEP-09	20090705	G	MD Investors Corporation. Metaldyne Corporation. Metaldyne Corporation.
		G	
		G	
09-SEP-09	20090675	G	AT&T Inc. Paul G. Allen. Vulcan Spectrum LLC.
		G	
		G	
10-SEP-09	20090649	G	Voting Shares Trust.

¹ Copies of the Minutes of the Federal Open Market Committee at its meeting held on September 22 and 23, 2009, which includes the domestic

policy directive issued at the meeting, are available upon request to the Board of Governors of the Federal Reserve System, Washington, D.C. 20551.

The minutes are published in the Federal Reserve Bulletin and in the Board's annual report.

TRANSACTION GRANTED EARLY TERMINATION—Continued

ET date	Trans No.	ET req status	Party name
14-SEP-09	20090651	G	Metagenics, Inc.
		G	Metagenics, Inc.
		G	Meyer Burger Technology Ltd.
	20090652	G	Diamond Wire Technology, LLC.
		G	Diamond Wire Technology, LLC.
		G	Richard M. DeVos.
	20090711	G	Metagenics, Inc.
		G	Metagenics, Inc.
		G	Howard D. Schultz.
	20090712	G	Starbucks Corporation.
		G	Starbucks Corporation.
		G	Leonard A. Lauder.
	20090715	G	The Estee Lauder Companies Inc.
		G	The Estee Lauder Companies Inc.
		G	Advent CR Holdings, Inc.
	20090717	G	Charlotte Russe Holding, Inc.
		G	Charlotte Russe Holding, Inc.
		G	Kinder Morgan Energy Partners, L.P.
	20090718	G	Crosstex Energy, L.P.
G		Crosstex Treating Services, L.P.	
G		Big River Resources, LLC.	
20090719	G	RBF Acquisition III, LLC.	
	G	RBF Acquisition III, LLC.	
	G	TCV VII, LP.	
20090721	G	HomeAway, Inc.	
	G	HomeAway, Inc.	
	G	Associated Food Stores, Inc.	
20090722	G	SUPERVALU INC.	
	G	New Albertson's, Inc.	
	G	Murphy Oil Corporation.	
20090724	G	RBF Acquisition IV, LLC.	
	G	RBF Acquisition IV, LLC.	
	G	Quanta Services, Inc.	
20090726	G	Price Gregory Services, Inc.	
	G	Price Gregory Services, Inc.	
	G	Terra Firma Capital Partners III, L.P.	
5-SEP-09	20090713	G	EverPower Wind Holdings, Inc.
		G	EverPower Wind Holdings, Inc.
		G	Comvest Investment Partners III, LP.
6-SEP-09	20090710	G	Cynergy Data, LLC.
		G	Cynergy Data, LLC.
		G	SPO Partners II, L.P.
21-SEP-09	20090678	G	Resolute Energy Corporation.
		G	Resolute Energy Corporation.
		G	Google Inc.
22-SEP-09	20090685	G	On2 Technologies, Inc.
		G	On2 Technologies, Inc.
		G	Providence Equity Partners VI International L.P.
20090686	20090686	G	Ares Corporate Opportunities Fund II, L.P.
		G	Stream Global Services, Inc.
		G	Mermac, Inc.
20090745	20090745	G	Ares Corporate Opportunities Fund II, L.P.
		G	Stream Global Services, Inc.
		G	TA X L.P.
23-SEP-09	20090720	G	Wellspring Capital Partners III, L.P.
		G	Vatterott Education Holding, Inc.
		G	Agropur Cooperative.
20090766	20090766	G	Mr. Martin J. Margherio.
		G	Asceptic Newco LLC.
		G	Berkshire Fund VII, L.P.
25-SEP-09	20090384	G	United BioSource Corporation.
		G	United BioSource Corporation.
		G	K + S Aktiengesellschaft.
20090412	20090412	G	The Dow Chemical Company.
		G	Morton International, Inc.
		G	Rohm and Haas Denmark China Salt Holdings ApS.
20090735	20090735	G	Dean Foods Company.
		G	Jack H. Brown.
		G	Santee Dairies, LLC.
		G	Rocket Software, Inc.
		G	International Business Machines Corporation.

TRANSACTION GRANTED EARLY TERMINATION—Continued

ET date	Trans No.	ET req status	Party name
28-SEP-09	20090747	G	International Business Machines Corporation.
		G	Court Square Capital Partners II, L.P.
		G	Rocket Software, Inc.
	20090757	G	Rocket Software, Inc.
		G	H.I.G. Capital Partners IV, L.P.
		G	Stant Parent Corp.
		G	Standard-Thomson Corporation.
		G	Stant Holding Corp.
		G	Thomson International Corporation.
	20090770	G	Stant Manufacturing, Inc.
		G	Stant Corporation.
		G	M. Brooks Smith.
	20090771	G	Ami Shashoua.
		G	QPay, Inc.
		G	M. Brooks Smith.
29-SEP-09	20090742	G	Yossi Amossy.
		G	QPay, Inc.
		G	Hon Hai Precision Industry Co., Ltd.
30-SEP-09	20090732	G	Sony Corporation.
		G	Sony Electronics Inc.
		G	Sony Baja California, SA. de C.V.
		G	Warner Chilcott plc.
		G	The Procter & Gamble Company.
		G	Procter & Gamble Pharmaceuticals Longjumeau SAS.
		G	Procter & Gamble S.p.A.
		G	Procter & Gamble Pharmaceuticals France SAS.
		G	Procter & Gamble Pharmaceuticals, Inc.
		G	Procter & Gamble Pharmaceuticals Germany GmbH.
		G	Procter & Gamble Pharmaceuticals S.a.r.l.
		G	Procter & Gamble Pharmaceuticals Iberia S.L.
20090752	G	Procter & Gamble Pharmaceuticals UK Limited.	
	G	LEO Fondet.	
	G	Peplin, Inc.	

FOR FURTHER INFORMATION CONTACT:
 Sandra M. Peay, Contact Representative,
 or Renee Hallman, Contact
 Representative, Federal Trade
 Commission, Premerger Notification
 Office, Bureau of Competition, Room H-
 303, Washington, DC 20580, (202) 326-
 3100.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. E9-25376 Filed 10-21-09; 8:45 am]

BILLING CODE 6750-01-M

FEDERAL TRADE COMMISSION

Granting of Request for Early Termination of the Waiting Period Under the Premerger Notification Rules

Section 7A of the Clayton Act, 15 U.S.C. 18a, as added by Title II of the Hart-Scott Rodino Antitrust Improvements Act of 1976, requires persons contemplating certain mergers or acquisitions to give the Federal Trade Commission and the Assistant Attorney General advance notice and to wait designated periods before consummation of such plans. Section

7A(b)(2) of the Act permits the agencies, in individual cases, to terminate this waiting period prior to its expiration and requires that notice of this action be published in the **Federal Register**.

The following transactions were granted early termination of the waiting period provided by law and the premerger notification rules. The grants were made by the Federal Trade Commission and the Assistant Attorney General for the Antitrust Division of the Department of Justice. Neither agency intends to take any action with respect to these proposed acquisitions during the applicable waiting period.

TRANSACTION GRANTED EARLY TERMINATION

ET date	Trans No.	ET req status	Party name
14-AUG-09	20090623	G	PartnerRe Ltd.
		G	PARIS RE Holdings Limited.
	20090627	G	PARIS RE Holdings Limited.
		G	Oglethorpe Power Corporation.
		G	International Power plc.
	20090630	G	Hartwell Energy Limited Partnership.
		G	Oglethorpe Power Corporation.
	20090644	G	Natural Gas Partners VIII, L.P.
		G	Hartwell Energy Limited Partnership.
		G	Career Education Corporation.

TRANSACTION GRANTED EARLY TERMINATION—Continued

ET date	Trans No.	ET req status	Party name	
18-AUG-09	20090648	G	Stitching LA Fondation Andre Cointreau.	
		G	Le Cordon Bleu International B.V.	
		G	McAfee, Inc.	
20-AUG-09	20090427	G	MX Logic, Inc.	
		G	MX Logic, Inc.	
		G	Arch Coal, Inc.	
21-AUG-09	20090448	G	Rio unto plc.	
		G	Jacobs Ranch Coal LLC.	
		G	Oracle Corporation.	
	20090655	G	Sun Microsystems, Inc.	
		G	Sun Microsystems, Inc.	
		G	Sprint Nextel Corporation.	
	24-AUG-09	20090657	G	Virgin Mobile USA, Inc.
			G	Virgin Mobile USA, Inc.
			G	ArcLight Energy Partners Fund III, L.P.
		20090661	G	PPL Corporation.
			G	PPL Maine, LLC.
			G	ArcLight Energy Partners Fund IV, L.P.
25-AUG-09		20090665	G	PPL Corporation.
			G	PPL Maine, LLC.
			G	Targa Resources Partners LP.
	20090647	G	Targa Resources Investments Inc.	
		G	Targa LSNG GP LLC.	
		G	Targa LSNG LP.	
	28-AUG-09	20090653	G	Targa Downstream GP LLC.
			G	Targa Downstream LP.
			G	Aetna Inc.
20090654		G	Psychiatric Solutions, Inc.	
		G	Horizon Behavioral Services, LLC.	
		G	Manulife Financial Corporation.	
01-SEP-09		20090664	G	PPL Corporation.
			G	PPL Edgewood Energy, LLC.
			G	PPL Shoreham Energy, LLC.
	20090645	G	Electric Power Development Co., Ltd.	
		G	PPL Corporation.	
		G	PPL Edgewood Energy, LLC.	
	02-SEP-09	20090666	G	PPL Shoreham Energy, LLC.
			G	Sentara Healthcare.
			G	Potomac Hospital Foundation.
20090672		G	Potomac Hospital Corporation of Prince William.	
		G	lochpe-Maxion S.A.	
		G	ArvinMeritor, Inc.	
01-SEP-09		20090676	G	ArvinMeritor OE, LLC.
			G	Meritor LVS S.A. de C.V.
			G	Servicios Corporativos ArvinMeritor, S.A. de C.V.
	20090626	G	Meritor Comercio Industria de Sistemas Automotivos Ltda.	
		G	JPMorgan Chase & Co.	
		G	ArthroCare Corporation.	
	02-SEP-09	20090677	G	ArthroCare Corporation.
			G	Noble Group Limited.
			G	SemGroup, L.P.-Debtor-in-Possession.
20090687		G	SemFuel, L.P.-Debtor-in-Possession.	
		G	Kurosawa B.V.	
		G	William B. Dunavant, Jr.	
02-SEP-09		20090679	G	Dunavant Enterprises, Inc.
			G	Frontier Communications Corporation.
			G	Verizon Communications Inc.
	20090680	G	New Communications Holdings, Inc.	
		G	Inverness Medical Innovations, Inc.	
		G	Free & Clear, Inc.	
	02-SEP-09	20090679	G	Free & Clear, Inc.
			G	LS Power Equity Partners II, L.P.
			G	Dynegy, Inc.
20090680		G	Sandy Creek Services, LLC.	
		G	Riverside Generating Company, L.L.C.	
		G	Renaissance Power, LLC.	
20090680		G	Bridgeport Energy LLC.	
		G	Bluegrass Generation Company, L.L.C.	
		G	Dynegy Sandy Creek Holdings, LLC.	
20090680	G	LS Power Equity Partners, L.P.		
	G	Dynegy, Inc.		
	G	Dynegy, Inc.		

TRANSACTION GRANTED EARLY TERMINATION—Continued

ET date	Trans No.	ET req status	Party name
03-SEP-09	20090690	G	Tilton Energy LLC.
		G	Griffith Energy LLC.
		G	Dynegy Arlington Valley, LLC.
		G	Rocky Road Power, LLC.
		G	General Motors Company.
04-SEP-09	20090401	G	Delphi Corporation.
		G	DIP Holdco LLP.
		G	Fidelity National Information Services, Inc.
		G	Metavante Technologies, Inc.
		G	Metavante Technologies, Inc.
04-SEP-09	20090697	G	Electric Power Development Co., Ltd.
		G	General Electric Company.
		G	Birchwood Power Partners, L.P.
		G	Joe and Marlene Ricketts Grandchildren's Trust.
		G	Tribune Company.
04-SEP-09	20090702	G	Chicago Baseball Holdings, LLC.
		G	STG III, L.P.
		G	MSC Software Corporation.
		G	MSC Software Corporation.
		G	MSC Software Corporation.
04-SEP-09	20090704	G	MSC Software Corporation.
		G	MSC Software Corporation.
		G	MSC Software Corporation.
		G	MSC Software Corporation.
		G	MSC Software Corporation.

FOR FURTHER INFORMATION CONTACT: Sandra M. Peay, Contact Representative, or Renee Hallman, Contact Representative, Federal Trade Commission, Premerger Notification Office, Bureau of Competition, Room H-303, Washington, DC 20580, (202) 326-3100.

By direction of the Commission.
Donald S. Clark,
Secretary.
 [FR Doc. E9-25377 Filed 10-21-09; 8:45 am]
BILLING CODE 6750-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
 [Docket No. FDA-2009-N-0474]

Agency Information Collection Activities; Proposed Collection; Comment Request; Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002

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 the publication of the criteria FDA intends to use to accredit third parties to conduct inspections of eligible manufacturers of class II or class III medical devices.

DATES: Submit written or electronic comments on the collection of information by December 21, 2009.

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: Denver Presley, Jr., Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3793.

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.

Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002; FD&C Act, Section 704(g) (OMB Control Number 0910-0510)—Extension

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250) was signed into law on October 26, 2002. Section 201 of MDUFMA adds a new paragraph "g" to section 704 of the Federal, Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 374), directing FDA to accredit third parties (accredited persons (APs)) to conduct inspections of eligible manufacturers of class II or class III devices. This is a voluntary program.

FDA has a guidance document that provides information for those interested in participating in this program. The guidance is entitled

“Implementation of the Inspection by Accredited Persons Program Under the Medical Device User Fee and

Modernization Act of 2002; Accreditation Criteria.”

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

FD&C Act Section:	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
704(g)	3	1	3	80	240

¹ There are no capital costs or operating and maintenance costs associated with this collection of information

FDA based these estimates on conversations with industry, trade association representatives, and internal FDA estimates. Once an organization is accredited, it will not be required to reapply.

Dated: October 7, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–25395 Filed 10–21–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Establishment

Pursuant to the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), the Director, National Institutes of Health (NIH), announces the establishment of the Interdisciplinary Molecular Sciences and Training Integrated Review Group (IRG).

The IRG shall advise the Director, National Institutes of Health (NIH), and the Director, Center for Scientific Review (CSR), on the scientific and technical merit of applications for grants-in-aid for research, research training or research-related grants and cooperative agreements, or contract proposals relating to scientific areas relevant to biological chemistry, biophysics and cell biology, drug discovery and development, devices and detection systems, biomaterials, delivery systems and nanotechnology, computational biology, imaging and data mining, genes, genomes and genetics, environmental monitoring, and basic translational oncology.

Duration of this committee will be continuing with no specified end date.

Dated: October 9, 2009.

Francis S. Collins,

Director, National Institutes of Health.

[FR Doc. E9–25374 Filed 10–21–09; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–8039–N]

RIN 0938–AP48

Medicare Program; Medicare Part B Monthly Actuarial Rates, Premium Rate, and Annual Deductible Beginning January 1, 2010

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces the monthly actuarial rates for aged (age 65 and over) and disabled (under age 65) beneficiaries enrolled in Part B of the Medicare Supplementary Medical Insurance (SMI) program beginning January 1, 2010. In addition, this notice announces the monthly premium for aged and disabled beneficiaries as well as the income-related monthly adjustment amounts to be paid by beneficiaries with modified adjusted gross income above certain threshold amounts. The monthly actuarial rates for 2010 are \$221.00 for aged enrollees and \$270.40 for disabled enrollees. The standard monthly Part B premium rate for 2010 is \$110.50, which is equal to 50 percent of the monthly actuarial rate for aged enrollees or roughly 25 percent of the expected average total cost of Part B coverage for aged enrollees. (The 2009 standard premium rate was \$96.40.) The Part B deductible for 2010 is \$155.00 for all Part B beneficiaries. A beneficiary who has to pay an income-related monthly adjustment may have to pay a total monthly premium of roughly 35, 50, 65 or 80 percent of the total cost of Part B coverage.

DATES: *Effective Date:* January 1, 2010.

FOR FURTHER INFORMATION CONTACT: M. Kent Clemens, (410) 786–6391.

SUPPLEMENTARY INFORMATION:

I. Background

Part B is the voluntary portion of the Medicare program that pays all or part

of the costs for physicians' services, outpatient hospital services, certain home health services, services furnished by rural health clinics, ambulatory surgical centers, comprehensive outpatient rehabilitation facilities, and certain other medical and health services not covered by Medicare Part A, Hospital Insurance. Medicare Part B is available to individuals who are entitled to Medicare Part A, as well as to U.S. residents who have attained age 65 and are citizens, and aliens who were lawfully admitted for permanent residence and have resided in the United States for 5 consecutive years. Part B requires enrollment and payment of monthly premiums, as provided for in 42 CFR part 407, subpart B, and part 408, respectively. Part B costs are met by payments from the Part B account of the Supplementary Medical Insurance Trust Fund, which is funded by the premiums paid by all enrollees and general revenues of the Federal Government.

The Secretary of the Department of Health and Human Services (the Secretary) is required by section 1839 of the Social Security Act (the Act) to announce the Part B monthly actuarial rates for aged and disabled beneficiaries as well as the monthly Part B premium. The Part B annual deductible is included because its determination is directly linked to the aged actuarial rate.

The monthly actuarial rates for aged and disabled enrollees are used to determine the correct amount of general revenue financing per beneficiary each month. These rates, according to actuarial estimates, will initially equal, respectively, one-half the expected average monthly cost of Part B for each aged enrollee (age 65 or over) and one-half the expected average monthly cost of Part B for each disabled enrollee (under age 65). The actuarial rates are then adjusted to include any margin necessary to maintain an adequate contingency reserve in the Part B account of the Supplementary Medical Insurance Trust Fund.

The Part B deductible to be paid by enrollees is also announced. Prior to the

Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), the Part B deductible was set in statute. After setting the 2005 deductible amount at \$110.00, section 629 of the MMA (amending section 1833(b) of the Act) requires that the Part B deductible be indexed beginning in 2006. The inflation factor to be used each year is the annual percentage increase in the Part B actuarial rate for enrollees age 65 and over. Specifically, the 2010 Part B deductible is calculated by multiplying the 2009 deductible by the ratio of the 2010 aged actuarial rate over the 2009 aged actuarial rate. The amount determined under this formula is then rounded to the nearest \$1.

The monthly Part B premium rate to be paid by aged and disabled enrollees is also announced. (Although the costs to the program per disabled enrollee are different than for the aged, the statute provides that they pay the same premium amount.) Beginning with the passage of section 203 of the Social Security Amendments of 1972 (Pub. L. 92–603), the premium rate, which was determined on a fiscal year basis, was limited to the lesser of the actuarial rate for aged enrollees, or the current monthly premium rate increased by the same percentage as the most recent general increase in monthly Title II Social Security benefits.

However, the passage of section 124 of the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) (Pub. L. 97–248) suspended this premium determination process. Section 124 of TEFRA changed the premium basis to 50 percent of the monthly actuarial rate for aged enrollees (that is, 25 percent of program costs for aged enrollees). Section 606 of the Social Security Amendments of 1983 (Pub. L. 98–21), section 2302 of the Deficit Reduction Act of 1984 (DEFRA 84) (Pub. L. 98–369), section 9313 of the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA 85) (Pub. L. 99–272), section 4080 of the Omnibus Budget Reconciliation Act of 1987 (OBRA 87) (Pub. L. 100–203), and section 6301 of the Omnibus Budget Reconciliation Act of 1989 (OBRA 89) (Pub. L. 101–239) extended the provision that the premium be based on 50 percent of the monthly actuarial rate for aged enrollees (that is, 25 percent of program costs for aged enrollees). This extension expired at the end of 1990.

The premium rate for 1991 through 1995 was legislated by section 1839(e)(1)(B) of the Act, as added by section 4301 of the Omnibus Budget Reconciliation Act of 1990 (OBRA 90) (Pub. L. 101–508). In January 1996, the

premium determination basis would have reverted to the method established by the 1972 Social Security Act Amendments. However, section 13571 of the Omnibus Budget Reconciliation Act of 1993 (OBRA 93) (Pub. L. 103–66) changed the premium basis to 50 percent of the monthly actuarial rate for aged enrollees (that is, 25 percent of program costs for aged enrollees) for 1996 through 1998.

Section 4571 of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) permanently extended the provision that the premium be based on 50 percent of the monthly actuarial rate for aged enrollees (that is, 25 percent of program costs for aged enrollees).

The BBA included a further provision affecting the calculation of the Part B actuarial rates and premiums for 1998 through 2003. Section 4611 of the BBA modified the home health benefit payable under Part A for individuals enrolled in Part B. Under this section, beginning in 1998, expenditures for home health services not considered “post-institutional” are payable under Part B rather than Part A. However, section 4611(e)(1) of the BBA required that there be a transition from 1998 through 2002 for the aggregate amount of the expenditures transferred from Part A to Part B. Section 4611(e)(2) of the BBA also provided a specific yearly proportion for the transferred funds. The proportions were $\frac{1}{6}$ for 1998, $\frac{1}{3}$ for 1999, $\frac{1}{2}$ for 2000, $\frac{2}{3}$ for 2001, and $\frac{5}{6}$ for 2002. For the purpose of determining the correct amount of financing from general revenues of the Federal Government, it was necessary to include only these transitional amounts in the monthly actuarial rates for both aged and disabled enrollees, rather than the total cost of the home health services being transferred.

Section 4611(e)(3) of the BBA also specified, for the purpose of determining the premium, that the monthly actuarial rate for enrollees age 65 and over be computed as though the transition would occur for 1998 through 2003 and that $\frac{1}{7}$ of the cost be transferred in 1998, $\frac{2}{7}$ in 1999, $\frac{3}{7}$ in 2000, $\frac{4}{7}$ in 2001, $\frac{5}{7}$ in 2002, and $\frac{6}{7}$ in 2003. Therefore, the transition period for incorporating this home health transfer into the premium was 7 years while the transition period for including these services in the actuarial rate was 6 years.

Section 811 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173), also known as the Medicare Modernization Act, or MMA), which amended section 1839 of the Act, requires that, starting on January 1,

2007, the Part B premium a beneficiary pays each month be based on his or her annual income. Specifically, if a beneficiary’s “modified adjusted gross income” is greater than the legislated threshold amounts (for 2010, \$85,000 for a beneficiary filing an individual income tax return, and \$170,000 for a beneficiary filing a joint tax return) the beneficiary is responsible for a larger portion of the estimated total cost of Part B benefit coverage. In addition to the standard 25 percent premium, these beneficiaries have to pay an income-related monthly adjustment amount. The MMA made no change to the actuarial rate calculation, and the standard premium, which will continue to be paid by beneficiaries whose modified adjusted gross income is below the applicable thresholds, still represents approximately 25 percent of the estimated total cost to the program of Part B coverage for an aged enrollee. However, depending on income and tax filing status, a beneficiary could be responsible for 35, 50, 65 or 80 percent of the estimated total cost of Part B coverage, rather than 25 percent. The end result of the higher premium is that the Part B premium subsidy is reduced and less general revenue financing is required for beneficiaries with higher income because they are paying a larger share of the total cost with their premium. That is, the premium subsidy will continue to be approximately 75 percent for beneficiaries with income below the applicable income thresholds, but will be reduced for beneficiaries with income above these thresholds. The MMA specified that there be a 5-year transition to full implementation of this provision. However, section 5111 of the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171) modified the transition to a 3-year period. The full reduction in the Part B premium subsidy for beneficiaries with incomes above the applicable thresholds is in effect for calendar years 2009 and later.

Section 4732(c) of the BBA added section 1933(c) of the Act, which required the Secretary to allocate money from the Part B trust fund to the State Medicaid programs for the purpose of providing Medicare Part B premium assistance from 1998 through 2002 for the low-income Medicaid beneficiaries who qualify under section 1933 of the Act. This allocation, while not a benefit expenditure, was an expenditure of the trust fund and was included in calculating the Part B actuarial rates through 2002. For 2003 through 2010, the allocation was temporarily extended.

A further provision affecting the calculation of the Part B premium is

section 1839(f) of the Act, as amended by section 211 of the Medicare Catastrophic Coverage Act of 1988 (MCCA 88) (Pub. L. 100-360). (The Medicare Catastrophic Coverage Repeal Act of 1989 (Pub. L. 101-234) did not repeal the revisions to section 1839(f) made by MCCA 88.) Section 1839(f) of the Act, referred to as the “hold-harmless” provision, provides that if an individual is entitled to benefits under section 202 or 223 of the Act (the Old-Age and Survivors Insurance Benefit and the Disability Insurance Benefit, respectively) and has the Part B premiums deducted from these benefit payments, the premium increase will be reduced, if necessary, to avoid causing a decrease in the individual’s net monthly payment. This decrease in payment occurs if the increase in the individual’s social security benefit due to the cost-of-living adjustment under section 215(i) of the Act is less than the increase in the premium. Specifically, the reduction in the premium amount applies if the individual is entitled to benefits under section 202 or 223 of the Act for November and December of a particular year and the individual’s Part B premiums for December and the following January are deducted from the respective month’s section 202 or 223 benefits. The “hold-harmless” provision does not apply to beneficiaries who are required to pay an income-related monthly adjustment amount.

A check for benefits under section 202 or 223 of the Act is received in the month following the month for which

the benefits are due. The Part B premium that is deducted from a particular check is the Part B payment for the month in which the check is received. Therefore, a benefit check for November is not received until December, but has December’s Part B premium deducted from it.

Generally, if a beneficiary qualifies for hold-harmless protection, that is, if the beneficiary was in current payment status for November and December of the previous year, the reduced premium for the individual for that January and for each of the succeeding 11 months for which he or she is entitled to benefits, under section 202 or 203 of the Act, is the greater of the following—

- The monthly premium for January reduced as necessary to make the December monthly benefits, after the deduction of the Part B premium for January, at least equal to the preceding November’s monthly benefits, after the deduction of the Part B premium for December; or
- The monthly premium for that individual for that December.

In determining the premium limitations under section 1839(f) of the Act, the monthly benefits to which an individual is entitled under section 202 or 223 of the Act do not include retroactive adjustments or payments and deductions on account of work. Also, once the monthly premium amount is established under section 1839(f) of the Act, it will not be changed during the year even if there are retroactive adjustments or payments and deductions on account of work that

apply to the individual’s monthly benefits.

Individuals who have enrolled in Part B late or who have re-enrolled after the termination of a coverage period are subject to an increased premium under section 1839(b) of the Act. The increase is a percentage of the premium and is based on the new premium rate before any reductions under section 1839(f) of the Act are made.

II. Provisions of the Notice

A. Notice of Medicare Part B Monthly Actuarial Rates, Monthly Premium Rates, and Annual Deductible

The Medicare Part B monthly actuarial rates applicable for 2010 are \$221.00 for enrollees age 65 and over and \$270.40 for disabled enrollees under age 65. Section II.B. of this notice below, presents the actuarial assumptions and bases from which these rates are derived. The Part B standard monthly premium rate for 2010 is \$110.50. The Part B annual deductible for 2010 is \$155.00. Listed below are the 2010 Part B monthly premium rates to be paid by beneficiaries who file an individual tax return (including those who are single, head of household, qualifying widow(er) with dependent child, or married filing separately who lived apart from their spouse for the entire taxable year), or a joint tax return. (The income thresholds are indexed to the Consumer Price Index and rounded to the nearest \$1,000.)

Beneficiaries who file an individual tax return with income:	Beneficiaries who file a joint tax return with income:	Income-related monthly adjustment amount	Total monthly premium amount
Less than or equal to \$85,000	Less than or equal to \$170,000	\$0.00	\$110.50
Greater than \$85,000 and less than or equal to \$107,000.	Greater than \$170,000 and less than or equal to \$214,000.	44.20	154.70
Greater than \$107,000 and less than or equal to \$160,000.	Greater than \$214,000 and less than or equal to \$320,000.	110.50	221.00
Greater than \$160,000 and less than or equal to \$214,000.	Greater than \$320,000 and less than or equal to \$428,000.	176.80	287.30
Greater than \$214,000	Greater than \$428,000	243.10	353.60

In addition, the monthly premium rates to be paid by beneficiaries who are married and lived with their spouse at any time during the taxable year, but file a separate tax return from their spouse, are listed below.

Beneficiaries who are married and lived with their spouse at any time during the year, but file a separate tax return from their spouse:	Income-related monthly adjustment amount	Total monthly premium amount
Less than or equal to \$85,000	\$0.00	\$110.50
Greater than \$85,000 and less than or equal to \$129,000	176.80	287.30
Greater than \$129,000	243.10	353.60

The Part B annual deductible for 2010 is \$155.00 for all beneficiaries.

B. Statement of Actuarial Assumptions and Bases Employed in Determining the Monthly Actuarial Rates and the Monthly Premium Rate for Part B Beginning January 2010

1. Actuarial Status of the Part B Account in the Supplementary Medical Insurance Trust Fund

Under the statute, the starting point for determining the standard monthly premium is the amount that would be necessary to finance Part B on an incurred basis. This is the amount of income that would be sufficient to pay for services furnished during that year (including associated administrative costs) even though payment for some of

these services will not be made until after the close of the year. The portion of income required to cover benefits not paid until after the close of the year is added to the trust fund and used when needed.

The premium rates are established prospectively and are, therefore, subject to projection error. Additionally, legislation enacted after the financing was established, but effective for the period in which the financing is set, may affect program costs. As a result, the income to the program may not equal incurred costs. Therefore, trust fund assets must be maintained at a level that is adequate to cover an appropriate degree of variation between actual and projected costs, and the amount of incurred, but unpaid, expenses. Numerous factors determine

what level of assets is appropriate to cover variation between actual and projected costs. The three most important of these factors are: (1) The difference from prior years between the actual performance of the program and estimates made at the time financing was established; (2) the likelihood and potential magnitude of expenditure changes resulting from enactment of legislation affecting Part B costs in a year subsequent to the establishment of financing for that year, and (3) the expected relationship between incurred and cash expenditures. These factors are analyzed on an ongoing basis, as the trends can vary over time.

Table 1 summarizes the estimated actuarial status of the trust fund as of the end of the financing period for 2008 and 2009.

TABLE 1—ESTIMATED ACTUARIAL STATUS OF THE PART B ACCOUNT IN THE SUPPLEMENTARY MEDICAL INSURANCE TRUST FUND AS OF THE END OF THE FINANCING PERIOD

Financing period ending	Assets (millions)	Liabilities (millions)	Assets less liabilities (millions)
December 31, 2008	\$59,382	\$12,490	\$46,892
December 31, 2009	59,876	13,999	45,876

2. Monthly Actuarial Rate for Enrollees Age 65 and Older

The monthly actuarial rate for enrollees age 65 and older is one-half of the sum of monthly amounts for: (1) The projected cost of benefits; and (2) administrative expenses for each enrollee age 65 and older, after adjustments to this sum to allow for interest earnings on assets in the trust fund and an adequate contingency margin. The contingency margin is an amount appropriate to provide for possible variation between actual and projected costs and to amortize any surplus assets or unfunded liabilities.

The monthly actuarial rate for enrollees age 65 and older for 2010 is determined by first establishing per-enrollee cost by type of service from program data through 2008 and then projecting these costs for subsequent years. The projection factors used for financing periods from January 1, 2007 through December 31, 2010 are shown in Table 2.

As indicated in Table 3, the projected monthly rate required to pay for one-half of the total of benefits and administrative costs for enrollees age 65 and over for 2010 is \$189.84. Based on current estimates, the assets are not sufficient to cover the amount of incurred, but unpaid, expenses and to provide for a significant degree of variation between actual and projected

costs. Thus, a positive contingency margin is needed to increase assets to a more appropriate level. The monthly actuarial rate of \$221.00 provides an adjustment of \$34.32 for a contingency margin and -\$3.16 for interest earnings.

The size of the contingency margin for 2010 is affected by several factors. The first and largest factor involves current law formula for physician fees, which will result in a reduction in physician fees of approximately 21 percent in 2010 and is projected to cause additional reductions in subsequent years. Smaller scheduled reductions in physician payments have been legislatively avoided in every year since 2002. In recognition of the strong possibility of substantial increases in Part B expenditures that would result from similar legislation to override the decreases in physician fees in 2010 or later years, it is appropriate to maintain a significantly larger Part B contingency reserve than would otherwise be necessary. The asset level projected for the end of 2009 is not adequate to accommodate this contingency.

A second, much smaller factor underlying the need for an adequate contingency reserve, is the possibility for increased Part B costs in 2010 as a result of a serious flu season.

The third factor has a large impact on the level of the contingency reserve. As noted previously, for most Part B

beneficiaries the hold-harmless provision prevents their benefits under section 202 or 223 of the Act from decreasing as a result of an increase in the Part B premium. The increase in the benefits under section 202 and 223 of the Act is nearly certain to be 0 percent for 2010 and possibly for 2011. As a result, the increase in the Part B premium for 2010 (the \$14.10 increase from the 2009 standard monthly premium of \$96.40 to the 2010 standard monthly premium of \$110.50) will be paid by only a small percentage of Part B enrollees. (Approximately 27 percent of beneficiaries are not subject to the hold-harmless provision because they are subject to the income-related additional premium amount (5 percent), they are new enrollees during the year (3 percent), or they do not have their Part B premiums withheld from social security benefit payments (19 percent), including those who qualify for both Medicare and Medicaid and have their Part B premiums paid on their behalf by Medicaid (17 percent).) In order for Part B to be adequately funded in 2010, the 2010 contingency margin has been increased to account for this situation. However, the result is a larger-than-usual premium paid by or on behalf of a minority of Part B enrollees.

The traditional goal for the Part B reserve has been that assets minus liabilities at the end of a year should

represent between 15 and 20 percent of the following year's total incurred expenditures. Within this range, 17 percent has been the normal target. In view of the high probability that premiums and matching general revenues in 2010 will be inadequate, due to the hold-harmless provision, and the strong likelihood of actual expenditures exceeding estimated levels, due to the enactment of legislation after the financing has been set for a given year, a contingency reserve ratio in excess of 20 percent of the following year's expenditures would better ensure that the assets of the Part B account can adequately cover the cost of incurred-but-not-reported benefits together with variations between actual and estimated cost levels.

The actuarial rate of \$221.00 per month for aged beneficiaries, as announced in this notice for 2010, reflects the combined net effect of the factors described above and the projection assumptions listed in Table 2.

3. Monthly Actuarial Rate for Disabled Enrollees

Disabled enrollees are those persons under age 65 who are enrolled in Part B because of entitlement to Social Security disability benefits for more than 24 months or because of entitlement to Medicare under the end-stage renal disease (ESRD) program. Projected monthly costs for disabled enrollees (other than those with ESRD) are prepared in a fashion parallel to the projection for the aged using appropriate actuarial assumptions (see Table 2). Costs for the ESRD program are projected differently because of the

different nature of services offered by the program.

As shown in Table 4, the projected monthly rate required to pay for one-half of the total of benefits and administrative costs for disabled enrollees for 2010 is \$222.93. The monthly actuarial rate of \$270.40 also provides an adjustment of -\$3.64 for interest earnings and \$51.11 for a contingency margin, reflecting the same factors described above for the aged actuarial rate. Based on current estimates, the assets associated with the disabled Medicare beneficiaries are not sufficient to cover the amount of incurred, but unpaid, expenses and to provide for a significant degree of variation between actual and projected costs. Thus, a large contingency margin is needed to increase assets to an appropriate level.

The actuarial rate of \$270.40 per month for disabled beneficiaries, as announced in this notice for 2010, reflects the combined net effect of the factors described above for aged beneficiaries and the projection assumptions listed in Table 2.

4. Sensitivity Testing

Several factors contribute to uncertainty about future trends in medical care costs. It is appropriate to test the adequacy of the rates using alternative assumptions. The results of those assumptions are shown in Table 5. One set represents increases that are lower and, therefore, more optimistic than the current estimate. The other set represents increases that are higher and, therefore, more pessimistic than the current estimate. The values for the alternative assumptions were determined from a statistical analysis of

the historical variation in the respective increase factors.

As indicated in Table 5, the monthly actuarial rates would result in an excess of assets over liabilities of \$66,192 million by the end of December 2010 under the assumptions used in preparing this report. This amounts to 31 percent of the estimated total incurred expenditures for the following year.

Assumptions that are somewhat more pessimistic (and that therefore test the adequacy of the assets to accommodate projection errors) produce a surplus of \$42,525 million by the end of December 2010, which amounts to 18 percent of the estimated total incurred expenditures for the following year. Under fairly optimistic assumptions, the monthly actuarial rates would result in a surplus of \$89,783 million by the end of December 2010, or 47 percent of the estimated total incurred expenditures for the following year.

The above analysis indicates that the premium and general revenue financing established for 2010, together with existing Part B account assets would be adequate to cover estimated Part B costs for 2010 under current law, even if actual costs prove to be somewhat greater than expected.

5. Premium Rates and Deductible

As determined in accordance with section 1839 of the Act, listed below are the 2010 Part B monthly premium rates to be paid by beneficiaries who file an individual tax return (including those who are single, head of household, qualifying widow(er) with dependent child, or married filing separately who lived apart from their spouse for the entire taxable year), or a joint tax return.

Beneficiaries who file an individual tax return with income:	Beneficiaries who file a joint tax return with income:	Income-related monthly adjustment amount	Total monthly premium amount
Less than or equal to \$85,000	Less than or equal to \$170,000	\$0.00	\$110.50
Greater than \$85,000 and less than or equal to \$107,000.	Greater than \$170,000 and less than or equal to \$214,000.	44.20	154.70
Greater than \$107,000 and less than or equal to \$160,000.	Greater than \$214,000 and less than or equal to \$320,000.	110.50	221.00
Greater than \$160,000 and less than or equal to \$214,000.	Greater than \$320,000 and less than or equal to \$428,000.	176.80	287.30
Greater than \$214,000	Greater than \$428,000	243.10	353.60

In addition, the monthly premium rates to be paid by beneficiaries who are married and lived with their spouse at any time during the taxable year, but file a separate tax return from their spouse, are listed below.

Beneficiaries who are married and lived with their spouse at any time during the year, but file a separate tax return from their spouse:	Income-related monthly adjustment amount	Total monthly premium amount
Less than or equal to \$85,000	\$0.00	\$110.50
Greater than \$85,000 and less than or equal to \$129,000	176.80	287.30

Beneficiaries who are married and lived with their spouse at any time during the year, but file a separate tax return from their spouse:	Income-related monthly adjustment amount	Total monthly premium amount
Greater than \$129,000	243.10	353.60

TABLE 2—PROJECTION FACTORS¹12-MONTH PERIODS ENDING DECEMBER 31 OF 2007–2010
[In percent]

Calendar year	Physicians' services		Durable medical equipment	Carrier LAB ⁴	Other carrier services ⁵	Out-patient hospital	Home health agency	Hospital LAB ⁶	Other intermediary services ⁷	Managed care
	Fees ²	Residual ³								
<i>Aged:</i>										
2007	-1.4	3.5	2.9	9.8	4.7	8.5	18.8	3.2	8.4	3.6
2008	0.4	3.8	7.6	7.9	4.7	4.9	11.6	3.9	5.0	5.1
2009	1.7	4.0	-2.1	11.1	7.4	8.9	13.4	9.3	8.9	2.0
2010	-21.7	8.1	2.9	3.7	4.4	5.1	1.4	-1.7	5.1	-1.9
<i>Disabled:</i>										
2007	-1.4	3.4	3.6	13.1	6.7	8.8	20.7	6.1	8.8	4.5
2008	0.4	4.1	7.8	12.4	9.1	6.8	9.8	5.7	6.9	4.8
2009	1.7	5.5	1.3	15.6	10.0	9.6	14.2	10.4	9.6	1.9
2010	-21.7	8.1	3.2	3.6	3.6	5.1	1.8	-1.7	5.1	-2.1

¹ All values for services other than managed care are per fee-for-service enrollee. Managed care values are per managed care enrollee.
² As recognized for payment under the program.
³ Increase in the number of services received per enrollee and greater relative use of more expensive services.
⁴ Includes services paid under the lab fee schedule furnished in the physician's office or an independent lab.
⁵ Includes physician-administered drugs, ambulatory surgical center facility costs, ambulance services, parenteral and enteral drug costs, supplies, etc.
⁶ Includes services paid under the lab fee schedule furnished in the outpatient department of a hospital.
⁷ Includes services furnished in dialysis facilities, rural health clinics, Federally qualified health centers, rehabilitation and psychiatric hospitals, etc.

TABLE 3—DERIVATION OF MONTHLY ACTUARIAL RATE FOR ENROLLEES AGE 65 AND OVER FOR FINANCING PERIODS ENDING DECEMBER 31, 2007 THROUGH DECEMBER 31, 2010

	Financing periods			
	CY 2007	CY 2008	CY 2009	CY 2010
Covered services (at level recognized):				
Physician fee schedule	78.46	78.70	81.13	68.34
Durable medical equipment	9.65	9.99	9.53	9.75
Carrier lab ¹	3.96	4.11	4.45	4.59
Other carrier services ²	19.74	19.88	20.81	21.60
Outpatient hospital	29.87	30.18	32.03	33.48
Home health	9.84	10.57	11.67	11.76
Hospital lab ³	2.80	2.79	2.98	2.91
Other intermediary services ⁴	13.26	13.53	14.54	13.93
Managed care	41.93	49.89	54.74	54.51
Total services	209.51	219.65	231.87	220.87
Cost sharing:				
Deductible	-5.33	-5.49	-5.50	-6.32
Coinsurance	-30.74	-30.31	-31.42	-28.29
Total benefits	173.44	183.84	194.95	186.26
Administrative expenses	5.68	2.95	3.41	3.58
Incurred expenditures	179.12	186.79	198.36	189.84
Value of interest	-1.98	-3.35	-2.83	-3.16
Contingency margin for projection error and to amortize the surplus or deficit	9.86	9.26	-2.83	34.32
Monthly actuarial rate	187.00	192.70	192.70	221.00

¹ Includes services paid under the lab fee schedule furnished in the physician's office or an independent lab.
² Includes physician-administered drugs, ambulatory surgical center facility costs, ambulance services, parenteral and enteral drug costs, supplies, etc.
³ Includes services paid under the lab fee schedule furnished in the outpatient department of a hospital.
⁴ Includes services furnished in dialysis facilities, rural health clinics, Federally qualified health centers, and rehabilitation and psychiatric hospitals, etc.

TABLE 4—DERIVATION OF MONTHLY ACTUARIAL RATE FOR DISABLED ENROLLEES FOR FINANCING PERIODS ENDING DECEMBER 31, 2007 THROUGH DECEMBER 31, 2010

	Financing periods			
	CY 2007	CY 2008	CY 2009	CY 2010
Covered services (at level recognized):				
Physician fee schedule	78.44	79.83	84.46	71.37
Durable medical equipment	16.95	17.76	17.76	18.29
Carrier lab ¹	5.00	5.41	6.10	6.31
Other carrier services ²	23.11	24.47	26.57	27.45
Outpatient hospital	40.10	41.44	44.75	46.92
Home health	8.24	8.79	9.89	10.05
Hospital lab ³	4.37	4.47	4.85	4.75
Other intermediary services ⁴	40.76	41.29	43.26	43.48
Managed care	29.87	36.50	39.83	39.49
Total services	246.85	259.96	277.47	268.11
Cost sharing:				
Deductible	- 5.00	- 5.11	- 5.15	- 5.92
Coinsurance	- 43.83	- 44.25	- 46.42	- 43.08
Total benefits	198.03	210.60	225.90	219.11
Administrative expenses	3.85	3.37	3.66	3.82
Incurred expenditures	201.88	213.97	229.56	222.93
Value of interest	- 3.37	- 4.32	- 3.29	- 3.64
Contingency margin for projection error and to amortize the surplus or deficit	- 1.21	0.05	- 2.07	51.11
Monthly actuarial rate	197.30	209.70	224.20	270.40

¹ Includes services paid under the lab fee schedule furnished in the physician's office or an independent lab.

² Includes physician-administered drugs, ambulatory surgical center facility costs, ambulance services, parenteral and enteral drug costs, supplies, etc.

³ Includes services paid under the lab fee schedule furnished in the outpatient department of a hospital.

⁴ Includes services furnished in dialysis facilities, rural health clinics, Federally qualified health centers, rehabilitation and psychiatric hospitals, etc.

TABLE 5—ACTUARIAL STATUS OF THE PART B ACCOUNT IN THE SMI TRUST FUND UNDER THREE SETS OF ASSUMPTIONS FOR FINANCING PERIODS THROUGH DECEMBER 31, 2010

As of December 31,	2008	2009	2010
This projection:			
Actuarial status (in millions):			
Assets	59,382	59,876	79,611
Liabilities	12,490	13,999	13,419
Assets less liabilities	46,892	45,876	66,192
Ratio (in percent) ¹	22.6	22.7	31.4
Low cost projection:			
Actuarial status (in millions):			
Assets	59,382	67,931	102,532
Liabilities	12,490	13,188	12,748
Assets less liabilities	46,892	54,744	89,783
Ratio (in percent) ¹	23.6	29.2	47.4
High cost projection:			
Actuarial status (in millions):			
Assets	59,382	52,148	56,681
Liabilities	12,490	14,778	14,156
Assets less liabilities	46,892	37,370	42,525
Ratio (in percent) ¹	21.8	17.2	18.2

¹ Ratio of assets less liabilities at the end of the year to the total incurred expenditures during the following year, expressed as a percent.

III. Regulatory Impact Analysis

We have examined the impacts of this notice as required by Executive Order

12866 on Regulatory Planning and Review (September 30, 1993), the Regulatory Flexibility Act (RFA)

(September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded

Mandates Reform Act of 1995 (Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any one year).

We have examined the impact of this notice as required by Executive Order 12866 (September 1993, Regulatory Planning and Review) and the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354). 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).

The RFA requires agencies to analyze options for regulatory relief of small businesses, if a rule has a significant impact on a substantial number of small

entities. For 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 million to \$34.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. Therefore, the Secretary has determined that this notice will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. The Secretary has determined that this notice will not have a significant impact on the operations of a substantial number of small rural hospitals. Therefore, we are not preparing analyses for either the RFA or section 1102(b) of the Act.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) 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 2008, that threshold is approximately \$133 million. This notice does not contain mandates that will impose spending costs on State, local or tribal governments in the aggregate, or by the private sector in any one year of \$133 million or more.

Executive Order 13132 establishes certain requirements that an agency must meet when it publishes a proposed rule (and subsequent final rule) that imposes substantial direct compliance costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have determined that this notice does not significantly affect the rights, roles, and responsibilities of States.

This notice announces that the monthly actuarial rates applicable for 2010 are \$221.00 for enrollees age 65 and over and \$270.40 for disabled enrollees under age 65. The Part B deductible for calendar year 2010 is \$155.00. The notice also announces the 2010 monthly Part B premium rates to be paid by beneficiaries who file an individual tax return (including those who are single, head of household, qualifying widow(er) with a dependent child, or married filing separately who lived apart from their spouse for the entire taxable year), or a joint tax return.

Beneficiaries who file an individual tax return with income:	Beneficiaries who file a joint tax return with income:	Income-related monthly adjustment amount	Total monthly premium amount
Less than or equal to \$85,000	Less than or equal to \$170,000	\$0.00	\$110.50
Greater than \$85,000 and less than or equal to \$107,000.	Greater than \$170,000 and less than or equal to \$214,000.	44.20	154.70
Greater than \$107,000 and less than or equal to \$160,000.	Greater than \$214,000 and less than or equal to \$320,000.	110.50	221.00
Greater than \$160,000 and less than or equal to \$214,000.	Greater than \$320,000 and less than or equal to \$428,000.	176.80	287.30
Greater than \$214,000	Greater than \$428,000	243.10	353.60

In addition, the monthly premium rates to be paid by beneficiaries who are married and lived with their spouse at any time during the taxable year, but file a separate tax return from their spouse, are also announced and listed below.

Beneficiaries who are married and lived with their spouse at any time during the year, but file a separate tax return from their spouse:	Income-related monthly adjustment amount	Total monthly premium amount
Less than or equal to \$85,000	\$0.00	\$110.50
Greater than \$85,000 and less than or equal to \$129,000	176.80	287.30
Greater than \$129,000	243.10	353.60

The standard Part B premium rate of \$110.50 is \$14.10 higher than the premium for 2009, so there will be about \$2 billion of additional costs in 2010 to the approximately 12 million Part B enrollees who pay the increase in

the Part B premium. Therefore, this notice is a major rule as defined in 5 U.S.C. 804(2) and is an economically significant rule under Executive Order 12866.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

IV. Waiver of Proposed Notice

The statute requires publication of the monthly actuarial rates and the Part B premium amounts. We ordinarily use general notices, rather than notice and comment rulemaking procedures, to make such announcements. In doing so, we note that, under the Administrative Procedure Act, interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice are excepted from the requirements of notice and comment rulemaking.

We considered publishing a proposed notice to provide a period for public comment. However, we may waive that procedure if we find, for good cause, that prior notice and comment are impracticable, unnecessary, or contrary to the public interest. We find that the procedure for notice and comment is unnecessary because the formulas used to calculate the Part B premiums are statutorily directed, and we can exercise no discretion in applying those formulas. Moreover, the statute establishes the time period for which the premium rates will apply, and delaying publication of the Part B premium rate such that it would not be published before that time would be contrary to the public interest. Therefore, we find good cause to waive publication of a proposed notice and solicitation of public comments.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: October 14, 2009.

Charlene Frizzera,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: October 16, 2009.

Kathleen Sebelius,

Secretary.

[FR Doc. E9–25370 Filed 10–16–09; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–8037–N]

RIN 0938–AP42

Medicare Program; Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for Calendar Year 2010

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces the inpatient hospital deductible and the hospital and extended care services coinsurance amounts for services furnished in calendar year (CY) 2010 under Medicare's Hospital Insurance Program (Medicare Part A). The Medicare statute specifies the formulae used to determine these amounts. For CY 2010, the inpatient hospital deductible will be \$1,100. The daily coinsurance amounts for CY 2010 will be—(a) \$275 for the 61st through 90th day of hospitalization in a benefit period; (b) \$550 for lifetime reserve days; and (c) \$137.50 for the 21st through 100th day of extended care services in a skilled nursing facility in a benefit period.

DATES: *Effective Date:* This notice is effective on January 1, 2010.

FOR FURTHER INFORMATION CONTACT: Clare McFarland, (410) 786–6390 for general information. Gregory J. Savord, (410) 786–1521 for case-mix analysis.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1813 of the Social Security Act (the Act) provides for an inpatient hospital deductible to be subtracted from the amount payable by Medicare for inpatient hospital services furnished to a beneficiary. It also provides for certain coinsurance amounts to be subtracted from the amounts payable by Medicare for inpatient hospital and extended care services. Section 1813(b)(2) of the Act requires us to determine and publish each year the amount of the inpatient hospital deductible and the hospital and extended care services coinsurance amounts applicable for services furnished in the following CY.

II. Computing the Inpatient Hospital Deductible for CY 2010

Section 1813(b) of the Act prescribes the method for computing the amount of the inpatient hospital deductible. The inpatient hospital deductible is an amount equal to the inpatient hospital deductible for the preceding CY, adjusted by our best estimate of the payment-weighted average of the applicable percentage increases (as defined in section 1886(b)(3)(B) of the Act) used for updating the payment rates to hospitals for discharges in the fiscal year (FY) that begins on October 1 of the same preceding CY, and adjusted to reflect changes in real case-mix. The adjustment to reflect real case-mix is determined on the basis of the most recent case-mix data available. The amount determined under this formula

is rounded to the nearest multiple of \$4 (or, if midway between two multiples of \$4, to the next higher multiple of \$4).

Under section 1886(b)(3)(B)(i)(XX) of the Act, the percentage increase used to update the payment rates for FY 2010 for hospitals paid under the inpatient prospective payment system is the market basket percentage increase, otherwise known as the market basket update. Under section 1886(b)(3)(B)(viii) of the Act, hospitals will receive the full market basket update only if they submit quality data as specified by the Secretary. The market basket update for hospitals that do not submit this data is reduced by 2.0 percentage points. We are estimating that after accounting for those hospitals receiving the lower market basket update in the payment-weighted average update, the calculated deductible will remain the same.

Under section 1886(b)(3)(B)(ii)(VIII) of the Act, the percentage increase used to update the payment rates for FY 2010 for hospitals excluded from the prospective payment system is the market basket percentage increase, defined according to section 1886(b)(3)(B)(iii) of the Act.

The market basket percentage increase for 2010 is 2.1 percent, as announced in the final rule with comment period published in the **Federal Register** on August 27, 2009 entitled, “Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and Fiscal Year 2010 Rates; and Changes to the Long-Term Care Hospital Prospective Payment System and Rate Years 2010 and 2009 Rates (IPPS/RY 2010 LTCH PPS) (74 FR 43754).” Therefore, the percentage increase for hospitals paid under the prospective payment system is 2.1 percent. The average payment percentage increase for hospitals excluded from the prospective payment system is 2.5 percent. Weighting these percentages in accordance with payment volume, our best estimate of the payment-weighted average of the increases in the payment rates for FY 2010 is 2.15 percent.

To develop the adjustment to reflect changes in real case-mix, we first calculated for each hospital an average case-mix that reflects the relative costliness of that hospital's mix of cases compared to those of other hospitals. We then computed the change in average case-mix for hospitals paid under the Medicare prospective payment system in FY 2009 compared to FY 2008. (We excluded from this calculation hospitals whose payments are not based on the Acute care prospective payment system because their payments are based on alternate

prospective payment systems or reasonable costs.) We used Medicare bills from prospective payment hospitals that we received as of June 2009. These bills represent a total of about 9.0 million Medicare discharges for FY 2009 and provide the most recent case-mix data available at this time. Based on these bills, the change in average case-mix in FY 2009 is 2.5 percent. Based on these bills and past experience, we expect the overall case mix change to be 3.1 percent as the year progresses and more FY 2009 data become available.

Section 1813 of the Act requires that the inpatient hospital deductible be adjusted only by that portion of the case-mix change that is determined to be real. In the FY 2010 IPPS/RY 2010 LTCH PPS final rule with comment period, we indicated that we believe the adoption of the Medicare severity-based diagnosis-related groups (MS-DRGs) led to increases in aggregate payments without a corresponding increase in actual patient severity of illness due to the incentives for improved documentation and coding. In that final rule with comment period, we estimated that changes in coding or classification

that do not reflect real change in case-mix would be 2.3 percent for FY 2009. Therefore, since we are expecting overall case mix to increase by 3.1 percent and 2.3 percent of that to be caused by coding changes, real case-mix changes resulted in an increase of 0.8 percent for FY 2009.

Thus, the estimate of the payment-weighted average of the applicable percentage increases used for updating the payment rates is 2.15 percent, and the real case-mix adjustment factor for the deductible is 0.8 percent. Therefore, under the statutory formula, the inpatient hospital deductible for services furnished in CY 2010 is \$1,100. This deductible amount is determined by multiplying \$1,068 (the inpatient hospital deductible for CY 2009) by the payment-weighted average increase in the payment rates of 1.0215 multiplied by the increase in real case-mix of 1.008, which equals \$1,099.69 and is rounded to \$1,100.

III. Computing the Inpatient Hospital and Extended Care Services Coinsurance Amounts for CY 2010

The coinsurance amounts provided for in section 1813 of the Act are

defined as fixed percentages of the inpatient hospital deductible for services furnished in the same CY. The increase in the deductible generates increases in the coinsurance amounts. For inpatient hospital and extended care services furnished in CY 2010, in accordance with the fixed percentages defined in the law, the daily coinsurance for the 61st through 90th day of hospitalization in a benefit period will be \$275 (one-fourth of the inpatient hospital deductible); the daily coinsurance for lifetime reserve days will be \$550 (one-half of the inpatient hospital deductible); and the daily coinsurance for the 21st through 100th day of extended care services in a skilled nursing facility in a benefit period will be \$137.50 (one-eighth of the inpatient hospital deductible).

IV. Cost to Medicare Beneficiaries

Table 1 below summarizes the deductible and coinsurance amounts for CYs 2009 and 2010, as well as the number of each that is estimated to be paid.

TABLE 1—PART A DEDUCTIBLE AND COINSURANCE AMOUNTS FOR CALENDAR YEARS 2009 AND 2010

Type of cost sharing	Value		Number paid (in millions)	
	2009	2010	2009	2010
Inpatient hospital deductible	\$1068	\$1100	8.70	8.80
Daily coinsurance for 61st–90th day	267	275	2.27	2.30
Daily coinsurance for lifetime reserve days	534	550	1.12	1.13
SNF coinsurance	133.50	137.50	40.79	41.74

The estimated total increase in costs to beneficiaries is about \$730 million (rounded to the nearest \$10 million) due to—(1) the increase in the deductible and coinsurance amounts; and (2) the change in the number of deductibles and daily coinsurance amounts paid.

V. Waiver of Proposed Notice and Comment Period

The Medicare statute, as discussed previously, requires publication of the Medicare Part A inpatient hospital deductible and the hospital and extended care services coinsurance amounts for services for each CY. The amounts are determined according to the statute. As has been our custom, we use general notices, rather than notice and comment rulemaking procedures, to make the announcements. In doing so, we acknowledge that, under the Administrative Procedure Act (APA), interpretive rules, general statements of policy, and rules of agency organization,

procedure, or practice are excepted from the requirements of notice and comment rulemaking.

We considered publishing a proposed notice to provide a period for public comment. However, we may waive that procedure if we find good cause that prior notice and comment are impracticable, unnecessary, or contrary to the public interest. We find that the procedure for notice and comment is unnecessary because the formulae used to calculate the inpatient hospital deductible and hospital and extended care services coinsurance amounts are statutorily directed, and we can exercise no discretion in following the formulae. Moreover, the statute establishes the time period for which the deductible and coinsurance amounts will apply and delaying publication would be contrary to the public interest. Therefore, we find good cause to waive publication of a proposed notice and solicitation of public comments.

VI. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

VII. Regulatory Impact Statement

We have examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the

Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). As stated in section IV of this notice, we estimate that the total increase in costs to beneficiaries associated with this notice is about \$730 million due to—(1) The increase in the deductible and coinsurance amounts; and (2) the change in the number of deductibles and daily coinsurance amounts paid. Therefore, this notice is a major rule as defined in Title 5, United States Code, section 804(2), and is an economically significant rule under Executive Order 12866.

The RFA requires agencies to analyze options for regulatory relief of small businesses, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$7.0 million to \$34.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. We have determined that this notice will not have a significant economic impact on a substantial number of small entities. Therefore, we are not preparing an analysis under the RFA.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. The Secretary has determined that this notice will not have a significant impact on the operations of a substantial number of small rural hospitals. Therefore, we are not preparing an analysis under section 1102(b) of the Act.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending

in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2009, that threshold is approximately \$133 million. This notice has no consequential effect on State, local, or Tribal governments or on the private sector. However, States may be required to pay the deductibles and coinsurance for dually-eligible beneficiaries.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This notice will not have a substantial effect on State or local governments.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance)

Dated: September 1, 2009.

Charlene Frizzera,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: September 17, 2009.

Kathleen Sebelius,

Secretary.

[FR Doc. E9-25372 Filed 10-16-09; 4:15 pm]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-8038-N]

RIN 0938-AP43

Medicare Program; Part A Premium for Calendar Year 2010 for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This annual notice announces Medicare's Hospital Insurance (Part A) premium for uninsured enrollees in calendar year (CY) 2010. This premium is paid by enrollees age 65 and over who are not otherwise eligible for benefits under Medicare Part A (hereafter known as the "uninsured aged") and by certain disabled individuals who have exhausted other entitlement. The monthly Part A premium for the 12 months beginning January 1, 2010 for

these individuals will be \$461. The reduced premium for certain other individuals as described in this notice will be \$254.

DATES: *Effective Date:* This notice is effective on January 1, 2010.

FOR FURTHER INFORMATION CONTACT: Clare McFarland, (410) 786-6390.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1818 of the Social Security Act (the Act) provides for voluntary enrollment in the Medicare Hospital Insurance Program (Medicare Part A), subject to payment of a monthly premium, of certain persons aged 65 and older who are uninsured under the Old-Age, Survivors, and Disability Insurance (OASDI) program or the Railroad Retirement Act and do not otherwise meet the requirements for entitlement to Medicare Part A. (Persons insured under the OASDI program or the Railroad Retirement Act and certain others do not have to pay premiums for Medicare Part A.)

Section 1818A of the Act provides for voluntary enrollment in Medicare Part A, subject to payment of a monthly premium of certain disabled individuals who have exhausted other entitlement. These are individuals who were entitled to coverage due to a disabling impairment under section 226(b) of the Act, but are no longer entitled to disability benefits and free Medicare Part A coverage because they have gone back to work and their earnings exceed the statutorily defined "substantial gainful activity" amount (section 223(d)(4) of the Act).

Section 1818A(d)(2) of the Act specifies that the provisions relating to premiums under section 1818(d) through section 1818(f) of the Act for the aged will also apply to certain disabled individuals as described above.

Section 1818(d) of the Act requires us to estimate, on an average per capita basis, the amount to be paid from the Federal Hospital Insurance Trust Fund for services incurred in the following calendar year (CY) (including the associated administrative costs) on behalf of individuals aged 65 and over who will be entitled to benefits under Medicare Part A. We must then determine, during September of each year, the monthly actuarial rate for the following year (the per capita amount estimated above divided by 12) and publish the dollar amount for the monthly premium in the succeeding CY. If the premium is not a multiple of \$1, the premium is rounded to the nearest multiple of \$1 (or, if it is a multiple of

50 cents but not of \$1, it is rounded to the next highest \$1).

Section 13508 of the Omnibus Budget Reconciliation Act of 1993 (Pub. L. 103-66) amended section 1818(d) of the Act to provide for a reduction in the premium amount for certain voluntary enrollees (section 1818 and section 1818A of the Act). The reduction applies to an individual who is eligible to buy into the Medicare Part A program and who, as of the last day of the previous month—

- Had at least 30 quarters of coverage under Title II of the Act;
- Was married, and had been married for the previous 1-year period, to a person who had at least 30 quarters of coverage;
- Had been married to a person for at least 1 year at the time of the person's death if, at the time of death, the person had at least 30 quarters of coverage; or
- Is divorced from a person and had been married to the person for at least 10 years at the time of the divorce if, at the time of the divorce, the person had at least 30 quarters of coverage.

Section 1818(d)(4)(A) of the Act specifies that the premium that these individuals will pay for CY 2010 will be equal to the premium for uninsured aged enrollees reduced by 45 percent.

II. Monthly Premium Amount for CY 2010

The monthly premium for the uninsured aged and certain disabled individuals who have exhausted other entitlement for the 12 months beginning January 1, 2010, is \$461.

The monthly premium for those individuals subject to the 45 percent reduction in the monthly premium is \$254.

III. Monthly Premium Rate Calculation

As discussed in section I of this notice, the monthly Medicare Part A premium is equal to the estimated monthly actuarial rate for CY 2010 rounded to the nearest multiple of \$1 and equals one-twelfth of the average per capita amount, which is determined by projecting the number of Part A enrollees aged 65 years and over as well as the benefits and administrative costs that will be incurred on their behalf.

The steps involved in projecting these future costs to the Federal Hospital Insurance Trust Fund are:

- Establishing the present cost of services furnished to beneficiaries, by type of service, to serve as a projection base;
- Projecting increases in payment amounts for each of the service types; and
- Projecting increases in administrative costs.

We base our projections for CY 2010 on—(1) current historical data; and (2) projection assumptions derived from current law and the Mid-Session Review of the President's Fiscal Year 2010 Budget.

We estimate that in CY 2010, 38,086,139 people aged 65 years and over will be entitled to benefits (without premium payment) and that they will incur about \$210.795 billion in benefits and related administrative costs. Thus, the estimated monthly average per capita amount is \$461.22 and the monthly premium is \$461. The full monthly premium reduced by 45 percent is \$254.

IV. Costs to Beneficiaries

The CY 2010 premium of \$461 is approximately 4 percent higher than the CY 2009 premium of \$443.

We estimate that approximately 558,000 enrollees will voluntarily enroll in Medicare Part A by paying the full premium. We estimate an additional 40,000 enrollees will pay the reduced premium. We estimate that the aggregate cost to enrollees paying these premiums will be about \$125 million in CY 2010 more than the amount that they paid in CY 2009.

V. Waiver of Proposed Notice and Comment Period

We are not using notice and comment rulemaking in this notification of Medicare Part A premiums for CY 2010, as that procedure is unnecessary because of the lack of discretion in the statutory formula that is used to calculate the premium and the solely ministerial function that this notice serves. The Administrative Procedure Act (APA) permits agencies to waive notice and comment rulemaking when notice and public comment thereon are unnecessary. On this basis, we waive publication of a proposed notice and a solicitation of public comments.

VI. Regulatory Impact Statement

We have examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select

regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). As stated in section IV of this notice, we estimate that the overall effect of these changes in the Part A premium will be an increased cost to voluntary enrollees (section 1818 and section 1818A of the Act) of about \$125 million. Therefore, this notice is a major rule as defined in Title 5, United States Code, section 804(2) and is an economically significant rule under Executive Order 12866.

The RFA requires agencies to analyze options for regulatory relief of small businesses, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$7 million to \$34.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. We have determined that this notice will not have a significant economic impact on a substantial number of small entities. Therefore, we are not preparing an analysis under the RFA.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. The Secretary has determined that this notice will not have a significant impact on the operations of a substantial number of small rural hospitals. Therefore, we are not preparing an analysis under section 1102(b) of the Act.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2009, that threshold is approximately \$133 million. This notice has no consequential effect on State, local, or tribal governments or on the private sector. However, States are required to

pay the premiums for dually-eligible beneficiaries.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This notice will not have a substantial effect on State or local governments.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance)

Dated: September 1, 2009.

Charlene Frizzera,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: September 17, 2009.

Kathleen Sebelius,

Secretary.

[FR Doc. E9-25371 Filed 10-16-09; 4:15 pm]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0664]

Radiological Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Radiological Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 17 and 18, 2009, from 8 a.m. to 5:30 p.m.

Location: Holiday Inn, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Toby Lowe, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-6512, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512526. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last

minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On November 17, 2009, the committee will discuss and make recommendations regarding the agency's regulatory strategy for Full Field Digital Mammography (FFDM) Devices. The committee will discuss the public comments received in response to the publication of the draft guidance document entitled "Class II Special Controls Guidance Document: Full Field Digital Mammography System." This guidance document can be found on the FDA Web site at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm107552.htm>.

On November 18, 2009, the committee will discuss and make recommendations regarding the agency's regulatory strategy for computer-assisted detection (CADE) devices for radiological devices. CADE devices are devices intended to identify, mark, highlight or in any other manner direct attention to potential abnormalities revealed in radiological data of the human body or imaging device data during interpretation of patient images or patient imaging data by a physician or other health care professional. The committee will discuss two draft guidance documents entitled "Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data—Premarket Notification [510(k)] Submissions" and "Clinical Performance Assessment: Considerations for Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data—Premarket Approval (PMA) and Premarket Notification [510(k)] Submissions." These guidance documents can be found on the FDA Web site at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments>. Type in the title of the guidance document included in this notice. The guidance documents will also be available as background materials.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before November 12, 2009. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on both

days. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before November 6, 2009. 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 November 9, 2009.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, Conference Management Staff, 301-796-5966, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 16, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9-25406 Filed 10-21-09; 8:45 am]

BILLING CODE 4160-01-S

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(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Scientific Management Review Board.

The NIH Reform Act of 2006 (Pub. L. 109-482) provides organizational authorities to HHS and NIH officials to: (1) Establish or abolish national research institutes; (2) reorganize the offices within the Office of the Director, NIH including adding, removing, or transferring the functions of such offices or establishing or terminating such offices; and (3) reorganize, divisions, centers, or other administrative units within an NIH national research

institute or national center including adding, removing, or transferring the functions of such units, or establishing or terminating such units. The purpose of the Scientific Management Review Board (also referred to as SMRB or Board) is to advise appropriate HHS and NIH officials on the use of these organizational authorities and identify the reasons underlying the recommendations.

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 notify the Contact Person listed below in advance of the meeting.

Name of Committee: Scientific Management Review Board.

Date: November 12–13, 2009.

Time: November 12, 2009, 1 p.m. to 5 p.m.

Agenda: Presentation and discussion will include updates from SMRB Working Groups: Deliberating Organizational Change and Effectiveness; NIH Intramural Research Program; and Substance Use, Abuse, and Addiction. There will also be time allotted on the agenda for public comment. Sign up for public comment will begin at approximately 12 p.m. In the event that time does not allow for all those interested to present oral comments, anyone may file written comments using the address below.

Place: National Institutes of Health, Building 31, 6th Floor, Conference Room 6, 31 Center Drive, Bethesda, MD 20892.

Time: November 13, 2009, 8:30 a.m. to 12 p.m.

Agenda: Continuation of November 12th meeting.

Place: National Institutes of Health, Building 31, 6th Floor, Conference Room 6, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Dr. Lyric Jorgenson, PhD, NIH-AAAS Science and Technology Policy Fellow, Office of Science Policy, Office of the Director, NIH, National Institutes of Health, Building 1 Room 218 MSC 0166, 9000 Rockville Pike, Bethesda, MD 20892, smrb@mail.nih.gov, (301) 496-6837.

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.

The meeting will also be webcast. The draft meeting agenda and other information about the SMRB, including information about access to the webcast, will be available at <http://smrb.od.nih.gov>.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxis, 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: October 15, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9-25403 Filed 10-21-09; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: AIDS and Related Research Integrated Review Group; AIDS Discovery and Development of Therapeutics Study Section.

Date: November 13, 2009.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: The Ritz Carlton Hotel, 1150 22nd Street, NW., Washington, DC 20037.

Contact Person: Shiv A. Prasad, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5220, MSC 7852, Bethesda, MD 20892, 301-443-5779, prasads@csr.nih.gov.

Name of Committee: AIDS and Related Research Integrated Review Group; NeuroAIDS and other End-Organ Diseases Study Section.

Date: November 13, 2009.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: InterContinental Mark Hopkins San Francisco, One Nob Hill, San Francisco, CA 94108.

Contact Person: Mary Clare Walker, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5208, MSC 7852, Bethesda, MD 20892, (301) 435-1165, walkermc@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business Grant Applications: Immunology.

Date: November 16–17, 2009.

Time: 8:30 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: The River Inn, 924 25th Street, NW., Washington, DC 20037.

Contact Person: Stephen M. Nigida, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4212, MSC 7812, Bethesda, MD 20892, 301-435-1222, nigidas@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business Innovation Research Grants.

Date: November 17, 2009.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Rass M. Shayiq, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2182, MSC 7818, Bethesda, MD 20892, (301) 435-2359, shayiqr@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 14, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9-25402 Filed 10-21-09; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; 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 Drug Abuse Special Emphasis Panel Production, Analysis and Distribution of Cannabis and Marijuana Cigarettes and Related Materials (7773).

Date: October 28, 2009.

Time: 1 p.m. to 2 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6101 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Scott Chen, PhD, Scientific Review Officer, Office of Extramural Affairs, National Institute on Drug Abuse, National Institutes of Health, DHHS, 6101 Executive Boulevard, Room 220, MSC 8401, Bethesda, MD 20892, 301-443-9511, chensc@mail.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. 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: October 15, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9-25375 Filed 10-21-09; 8:45 am]

BILLING CODE 4140-01-M

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, November 4, 2009, 8 a.m. to November 4, 2009, 5 p.m., Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD, 20814 which was published in the **Federal Register** on October 2, 2009, 74 FR 50975-50977.

The meeting will be held November 5, 2009. The meeting time and location remain the same. The meeting is closed to the public.

Dated: October 15, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9-25413 Filed 10-21-09; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Cardiovascular Regeneration.

Date: November 8-10, 2009.

Time: 4 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Virtual Meeting.)

Contact Person: Joseph Thomas Peterson, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118, MSC 7814, Bethesda, MD 20892. 301-443-8130.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Small Business: Biological Chemistry and Biophysics.

Time: November 9-10, 2009.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Sergei Ruvinov, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4158, MSC 7806, Bethesda, MD 20892. 301-435-1180. ruvinser@csr.nih.gov.

Name of Committee: AIDS and Related Research Integrated Review Group, AIDS Immunology and Pathogenesis Study Section.

Date: November 10, 2009.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Ritz Carlton Hotel, 1150 22nd Street, NW., Washington, DC 20037.

Contact Person: Shiv A. Prasad, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5220, MSC 7852, Bethesda, MD 20892. 301-443-5779. prasads@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Social Science and Population Studies.

Date: November 11-12, 2009.

Time: 4 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Westin St. Francis Hotel, 335 Powell Street, San Francisco, CA 94102.

Contact Person: Valerie Durrant, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3148, MSC 7770, Bethesda, MD 20892. (301) 435-3554. durrantv@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Small Business: Biomaterials, Delivery Systems, and Nanotechnology.

Date: November 13, 2009.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Alexander Gubin, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4196, MSC 7812, Bethesda, MD 20892. 301-435-2902. gubina@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, RFA-OD-09-008 BRDG-SPAN and RFA-OD-09-009 Catalyst ARRA Review Panel 7.

Date: November 17-18, 2009.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: William F. Bolger Center, 9600 Newbridge Drive, Potomac, MD 20854.

Contact Person: Rossana Berti, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3191, MSC 7846, Bethesda, MD 20892. 301-402-6411. bertiros@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, BRDG-SPAN and Catalyst ARRA Grants: Population Sciences and Epidemiology.

Date: November 18, 2009.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Suzanne Ryan, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3139, Bethesda, MD 20892. (301) 435-1712. ryansj@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Fellowship: Technology Development.

Date: November 19, 2009.

Time: 12 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Telephone Conference Call.)

Contact Person: Alessandra M. Bini, PhD, Scientific Review Officer, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5142, MSC 7840, Bethesda, MD 20892. 301-435-1024. binia@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 14, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9-25404 Filed 10-21-09; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Subcommittee for Dose Reconstruction Reviews (SDRR), Advisory Board on Radiation and Worker Health (ABRWH), National Institute for Occupational Safety and Health (NIOSH)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention, announces the following meeting for the aforementioned subcommittee:

Time and Date: 10 a.m.–5 p.m., November 5, 2009.

Place: Cincinnati Airport Marriott, 2395 Progress Drive, Hebron, Kentucky 41018, Telephone: (859) 334-4611, Fax: (859) 334-4619.

Status: Open to the public, but without a public comment period. To access by conference call dial the following information 1 (866) 659-0537, Participant Pass Code 9933701.

Background: The Advisory Board was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Advisory Board include providing advice on the development of probability of causation guidelines that have been promulgated by the Department of Health and Human Services (HHS) as a final rule; advice on methods of dose reconstruction which have also been promulgated by HHS as a final rule; advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program; and advice on

petitions to add classes of workers to the Special Exposure Cohort (SEC).

In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to CDC. NIOSH implements this responsibility for CDC. The charter was issued on August 3, 2001, renewed at appropriate intervals, and will expire on August 3, 2011.

Purpose: The Advisory Board is charged with (a) providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and (c) upon request by the Secretary, HHS, advise the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class. The Subcommittee for Dose Reconstruction Reviews was established to aid the Advisory Board in carrying out its duty to advise the Secretary, HHS, on dose reconstruction.

Matters To Be Discussed: The agenda for the Subcommittee meeting includes: discussion of dose reconstruction cases under review; OCAS dose reconstruction quality management and assurance activities.

The agenda is subject to change as priorities dictate.

In the event an individual cannot attend, written comments may be submitted. Any written comments received will be provided at the meeting and should be submitted to the contact person below well in advance of the meeting.

Contact Person for More Information: Theodore Katz, Executive Secretary, NIOSH, CDC, 1600 Clifton Road, Mailstop E-20, Atlanta GA 30333, Telephone: (513) 533-6800, Toll Free: 1 (800) CDC-INFO, e-mail ocas@cdc.gov.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: October 13, 2009.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E9-25390 Filed 10-21-09; 8:45 am]

BILLING CODE 4163-19-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Outcomes Research in Orthotics and Prosthetics.

Date: November 17, 2009.

Time: 10 a.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: Marriott Bethesda North, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Anne Krey, Scientific Review Officer, Division of Scientific Review, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, Bethesda, MD 20892, 301-435-6908.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: October 16, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9-25470 Filed 10-21-09; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; The Effect of HPV Vaccines on HPV Disease.

Date: October 29, 2009.

Time: 1:30 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817, (Telephone Conference Call)

Contact Person: Erica L. Brown, PhD, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, NIAID/NIH/DHHS, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892-7616, 301-451-2639, ebrown@niaid.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. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: October 16, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9-25469 Filed 10-21-09; 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 AIDS Clinical Studies and Epidemiology Study Section, November 17, 2009, 8 a.m. to November

18, 2009, 5 p.m., The Fairmont Washington, DC, 2401 M Street, NW., Washington, DC 20037 which was published in the **Federal Register** on October 9, 2009, 74 FR 52245-52246.

The meeting will be one day only November 17, 2009. The meeting time and location remain the same. The meeting is closed to the public.

Dated: October 15, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9-25412 Filed 10-21-09; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel; Career Development, Research Training & Pathways to Independence Review.

Date: November 3, 2009.

Time: 11 a.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Charles H Washabaugh, PhD, Scientific Review Officer, National Institute of Arthritis, Musculoskeletal and Skin Diseases, National Institutes of Health, 6701 Democracy Boulevard Suite 800, Bethesda, MD 20892, 301-594-4952, washabac@mail.nih.gov.

Name of Committee: National Institute of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel; Ancillary Clinical Studies.

Date: November 12, 2009.

Time: 9 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Charles H Washabaugh, PhD, Scientific Review Officer, 6701 Democracy Blvd, Suite 800, National Institute of Arthritis, Musculoskeletal and Skin Diseases, National Institutes of Health, Bethesda, MD 20892, (301) 594-4952, washabac@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: October 14, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9-25411 Filed 10-21-09; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Arthritis and Musculoskeletal and Skin Diseases Special Grants Review Committee.

Date: October 29-30, 2009.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Helen Lin, PhD, Scientific Review Officer, NIH/NIAMS/RB, 6701 Democracy Blvd., Suite 800, Plaza One, Bethesda, MD 20817, 301-594-4952, linh1@mail.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. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: October 14, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9-25410 Filed 10-21-09; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Board of Scientific Counselors, NIEHS.

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.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual grant applications conducted by the National Institute of Environmental Health Sciences, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, NIEHS.

Date: November 8–10, 2009.

Closed: November 8, 2009, 7 p.m. to 10 p.m.

Agenda: To review and evaluate programmatic and personnel issues.

Place: Doubletree Guest Suites, 2515 Meridian Parkway, Research Triangle Park, NC 27713.

Open: November 9, 2009, 8:30 a.m. to 2:30 p.m.

Agenda: An overview of the organization and research in the Laboratory of Molecular Genetics.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T. W. Alexander Drive, Conference Rooms 101 A, B, and C, Research Triangle Park, NC 27709.

Closed: November 9, 2009, 2:30 p.m. to 3:45 p.m.

Agenda: To review and evaluate programmatic and personnel issues.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T. W. Alexander Drive, Conference

Rooms 101 A, B, and C, Research Triangle Park, NC 27709.

Open: November 9, 2009, 4 p.m. to 5:40 p.m.

Agenda: An overview of the organization and research in the Laboratory of Molecular Genetics.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T. W. Alexander Drive, Conference Rooms 101 A, B, and C, Research Triangle Park, NC 27709.

Closed: November 9, 2009, 5:40 p.m. to 6:10 p.m.

Agenda: To review and evaluate programmatic and personnel issues.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T. W. Alexander Drive, Conference Rooms 101 A, B, and C, Research Triangle Park, NC 27709.

Closed: November 9, 2009, 6:15 p.m. to Adjournment.

Agenda: To review and evaluate programmatic and personnel issues.

Place: Doubletree Guest Suites, 2515 Meridian Parkway, Research Triangle Park, NC 27713.

Open: November 10, 2009, 8:30 a.m. to 10:30 a.m.

Agenda: An overview of the organization and research in the Laboratory of Molecular Genetics.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T. W. Alexander Drive, Conference Rooms 101 A, B, and C, Research Triangle Park, NC 27709.

Closed: November 10, 2009, 10:30 a.m. to 12 p.m.

Agenda: To review and evaluate programmatic and personnel issues.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T. W. Alexander Drive, Conference Rooms 101 A, B, and C, Research Triangle Park, NC 27709.

Contact Person: John B. Pritchard, Acting Scientific Director, Office of the Director, National Institute of Environmental Health Sciences, 111 T.W. Alexander Drive, Research Triangle Park, NC 27709-2233, (919) 541-4054, pritcha3@niehs.nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: October 14, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9-25408 Filed 10-21-09; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Psychopathology, Developmental Disabilities, Stress and Aging.

Date: November 6, 2009.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Monticello, 1075 Thomas Jefferson Street, NW., Washington, DC 20007.

Contact Person: Kathlyn Robbins, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3182, MSC 7848, Bethesda, MD 20892, (301) 435-0913, robbsink@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Cognition, Language and Perception Fellowship Study Section.

Date: November 13, 2009.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: The Fairmont Washington, DC., 2401 M Street, NW., Washington, DC 20037.

Contact Person: Weijia Ni, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3184, MSC 7848, Bethesda, MD 20892, (301) 435-1507, niw@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA-OD-09-008 BRDG-SPAN and RFA-OD-09-009 Catalyst ARRA Review Panel 2.

Date: November 23, 2009.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Lawrence E. Boerboom, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5156, MSC 7814, Bethesda, MD 20892, (301) 435-8367, boerboom@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 14, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9-25405 Filed 10-21-09; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; ARRA AREA Special Emphasis Panel 07.

Date: November 17, 2009.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Beacon Hotel and Corporate Quarters, 1615 Rhode Island Avenue, NW., Washington, DC 20036.

Contact Person: Rolf Menzel, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3196, MSC 7808, Bethesda, MD 20892, 301-435-0952, menzelro@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA-OD-09-008 BRDG-SPAN and RFA-OD-09-009 Catalyst ARRA Review Panel 8.

Date: November 23, 2009.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: The Fairmont Washington, DC, 2401 M Street, NW., Washington, DC 20037.

Contact Person: Ross D. Shonat, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5156, MSC 7849, Bethesda, MD 20892, 301-435-2786, shonatr@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 15, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9-25471 Filed 10-21-09; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Comment: National Center for Complementary and Alternative Medicine Announcement of Strategic Planning Background Papers

ACTION: Notice.

SUMMARY: The National Center for Complementary and Alternative Medicine (NCCAM) is developing its third strategic plan and invites the public to provide comments on three background papers which will support the development of this plan. The papers will cover three topics: Mission, priority setting, and communications and decisionmaking. They will be publicly available through the NCCAM Web site at from on or about October 19 through November 19, 2009. The public is invited to provide comments through the NCCAM Web site.

Background: The National Center for Complementary and Alternative Medicine (NCCAM) was established in 1998 with the mission of exploring complementary and alternative healing practices in the context of rigorous science, training CAM researchers, and disseminating authoritative information to the public and professionals.

To date, NCCAM's efforts to rigorously study CAM, to train CAM researchers, and to communicate with the public and professionals, have been guided by NCCAM's previous strategic plans, located on the NCCAM Web site at <http://nccam.nih.gov/about/plans>.

The public is invited to review the background papers and provide comments from October 15 through November 15, 2009. The papers may be viewed at <http://nccam.nih.gov/>.

Request For Comments: The public is invited to provide comments on the

three background papers that will support the development of NCCAM's third strategic plan. Comments may be provided through the NCCAM Web site at <http://nccam.nih.gov>.

For Further Information: To request more information, visit the NCCAM Web site at <http://nccam.nih.gov>, call 1-888-644-6226, or e-mail

<ncamsp@mail.nih.gov>

Comments Due Date: Comments regarding the draft of NCCAM's strategic plan are best assured of having their full effect if received by November 19, 2009.

Dated: October 13, 2009.

Jack Killen,

Deputy Director, National Center for Complementary and Alternative Medicine, National Institutes of Health.

[FR Doc. E9-25307 Filed 10-21-09; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0664]

Request for Notification From Industry Organizations Interested in Participating in Selection Process for Nonvoting Industry Representatives on Public Advisory Committees and Request for Nominations for Nonvoting Industry Representatives on Public Advisory Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that any industry organizations interested in participating in the selection of nonvoting industry representatives to serve on its public advisory committees for the Center for Food Safety and Applied Nutrition (CFSAN) notify FDA in writing. FDA is also requesting nominations for nonvoting industry representatives to serve on CFSAN's Food Advisory Committee. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for current vacancies effective with this notice.

DATES: Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating that interest to FDA by November 23, 2009, for vacancies listed in this notice. Concurrently, nomination materials for

prospective candidates should be sent to FDA by November 23, 2009.

ADDRESSES: All letters of interest and nominations should be submitted in writing to Carolyn Jeletic (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Carolyn Jeletic, Center for Food Safety and Applied Nutrition, Office of Regulations, Policy, and Social Sciences (HFS-024), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1913, carolyn.jeletic@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations, and a list of all nominees along with their current resumes. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for a particular committee. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner of Food and Drugs will select the nonvoting member to represent industry interests.

II. Application Procedure

Individuals may self nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. A current curriculum vitae and the name of the committee of interest should be sent to the FDA contact person within the 30 days. FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process).

FDA has a special interest in ensuring that women, minority groups, individuals with physical disabilities, and small businesses are adequately represented on its advisory committees, and therefore, encourages, nominations for appropriately qualified candidates

from these groups. Specifically, in this document, nominations for nonvoting representatives of industry interests are encouraged from the food production and manufacturing and industry, the dietary supplement manufacturing industry, the agricultural biotechnology manufacturing industry.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: October 16, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9-25407 Filed 10-21-09; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA-2009-0001]

Agency Information Collection Activities: Submission for OMB Review; Comment Request, OMB No. 1660-0099

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice; 30-day notice and request for comments; revision of a currently approved information collection; OMB No. 1660-0099; FEMA Form 646-0, Citizen Corps Individual Registration.

SUMMARY: The Federal Emergency Management Agency (FEMA) has submitted the information collection abstracted below to the Office of Management and Budget for review and clearance in accordance with the requirements of the Paperwork Reduction Act of 1995. The submission describes the nature of the information collection, the categories of respondents, the estimated burden (*i.e.*, the time, effort and resources used by respondents to respond) and cost, and the actual data collection instruments FEMA will use.

DATES: Comments must be submitted on or before November 23, 2009.

ADDRESSES: Submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the Desk Officer for the Department of Homeland Security, Federal Emergency Management Agency, and sent via electronic mail to

oir.submission@omb.eop.gov or faxed to (202) 395-5806.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection should be made to Director, Office of Records Management, 1800 South Bell Street, Arlington, VA 20598-3005, facsimile number (202) 646-3347, or e-mail address FEMA-Information-Collections@dhs.gov.

SUPPLEMENTARY INFORMATION:

Collection of Information

Title: Citizen Corps Individual Registration.

Type of information collection: Revision of a currently approved information collection.

OMB Number: OMB No. 1660-0099.

Form Titles and Numbers: FEMA Form 646-0, Citizen Corps Individual Registration.

Abstract: FEMA's Community Preparedness Division (CPD) would like to revise a currently approved collection for its individual registration to allow members of the public to provide contact information to receive national programmatic updates and announcements such as upcoming preparedness demonstrations and training opportunities and the opportunity to get involved in local organizations and events.

Affected Public: Individuals or households.

Estimated Number of Respondents: 20,000.

Frequency of Response: Once.

Estimated Average Hour Burden per Respondent: .08 burden hours.

Estimated Total Annual Burden Hours: 1,600 burden hours.

Estimated Cost: None.

Daisy Mitchell,

Acting Director, Records Management Division, Office of Management, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. E9-25378 Filed 10-21-09; 8:45 am]

BILLING CODE 9111-05-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA-2009-0001; OMB No. 1660-0098]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice; 30-day notice and request for comments; revision of a currently approved information collection; OMB No. 1660-0098; FEMA Form 646, Citizen Corps Council Registration.

SUMMARY: The Federal Emergency Management Agency (FEMA) has submitted the information collection abstracted below to the Office of Management and Budget for review and clearance in accordance with the requirements of the Paperwork Reduction Act of 1995. The submission describes the nature of the information collection, the categories of respondents, the estimated burden (*i.e.*, the time, effort and resources used by respondents to respond) and cost, and the actual data collection instruments FEMA will use.

DATES: Comments must be submitted on or before November 23, 2009.

ADDRESSES: Submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the Desk Officer for the Department of Homeland Security, Federal Emergency Management Agency, and sent via electronic mail to oir.submission@omb.eop.gov or faxed to (202) 395-5806.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection should be made to Director, Office of Records Management, 1800 South Bell Street, Arlington, VA 20598-3005, facsimile number (202) 646-3347, or e-mail address FEMA-Information-Collections@dhs.gov.

SUPPLEMENTARY INFORMATION:

Collection of Information

Title: Citizen Corps Council Registration.

Type of information collection: Revision of a currently approved information collection.

OMB Number: OMB No. 1660-0098.

Form Titles and Numbers: FEMA Form 646, Citizen Corps Council Registration.

Abstract: FEMA's Community Preparedness Division would like to revise a currently approved collection for its registration of State, local, Tribal and territorial Councils and Community Emergency Response Teams. The registration process allows for new Councils to submit information on the Council or CERT to the State Citizen Corps Program Manager for approval. The revised registration process will

allow for the collection of more valuable information and the tool is more user-friendly for Citizen Corps Councils and CERT's.

Affected Public: State, local or Tribal Government.

Estimated Number of Respondents: 5,759.

Frequency of Response: Semi-annually.

Estimated Average Hour Burden per Respondent: 2.

Estimated Total Annual Burden Hours: 11,518 burden hours.

Estimated Cost: None.

Daisy Mitchell,

Acting Director, Records Management Division, Office of Management, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. E9-25380 Filed 10-21-09; 8:45 am]

BILLING CODE 9111-05-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

Agency Information Collection Activities: Form N-445; Extension of an Existing Information Collection; Comment Request

ACTION: 60-Day Notice of Information Collection Under Review; Form N-445, Notice of Naturalization Oath Ceremony; OMB Control No. 1615-0054.

The Department Homeland Security, U.S. Citizenship and Immigration Services (USCIS) has submitted the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for sixty days until December 21, 2009.

During this 60 day period, USCIS will be evaluating whether to revise the Form N-445. Should USCIS decide to revise Form N-445 we will advise the public when we publish the 30-day notice in the **Federal Register** in accordance with the Paperwork Reduction Act. The public will then have 30 days to comment on any revisions to the Form N-445.

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Department of Homeland Security (DHS), USCIS, Chief, Regulatory

Products Division, Clearance Officer, 111 Massachusetts Avenue, NW., Washington, DC 20529-2210.

Comments may also be submitted to DHS via facsimile to 202-272-8352 or via e-mail at rfs.regs@dhs.gov. When submitting comments by e-mail, please make sure to add OMB Control No. 1615-0054 in the subject box. Written comments and suggestions from the public and affected agencies concerning the collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this Information Collection

(1) *Type of Information Collection:* Extension of an existing information collection.

(2) *Title of the Form/Collection:* Notice of Naturalization Oath Ceremony.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form N-445; U.S. Citizenship and Immigration Services (USCIS).

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. The information furnished on Form N-445 refers to events that may have occurred since the applicant's initial interview and prior to the administration of the oath of allegiance. Several months may elapse between these dates and the information that is provided assists the officer to make and render an appropriate decision on the application.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 650,000 responses at 10 minutes (.166) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 107,900 annual burden hours.

If you need a copy of the information collection instrument, please visit the Web site at: <http://www.regulations.gov/>.

We may also be contacted at: USCIS, Regulatory Products Division, 111 Massachusetts Avenue, NW., Washington, DC 20529-2210, Telephone number 202-272-8377.

Dated: October 16, 2009.

Sunday Aigbe,

Chief, Regulatory Products Division, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. E9-25394 Filed 10-21-09; 8:45 am]

BILLING CODE 9111-97-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA-1858-DR; Docket ID FEMA-2008-0018]

Georgia; Amendment No. 7 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Georgia (FEMA-1858-DR), dated September 24, 2009, and related determinations.

DATES: *Effective Date:* October 8, 2009.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Disaster Assistance Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-3886.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the incident period for this disaster is closed effective October 8, 2009.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals

and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.)

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. E9-25388 Filed 10-21-09; 8:45 am]

BILLING CODE 9111-23-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-5288-N-14]

Notice of Submission of Proposed Information Collection to OMB; Section 8 Management Assessment Program (SEMAP)

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* December 21, 2009.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name/or OMB Control number and should be sent to: Lillian L. Deitzer, Departmental Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street, SW., Room 4178, Washington, DC 20410-5000; telephone 202-402-8048, (this is not a toll-free number) or email Ms. Deitzer at Lillian.L.Deitzer@hud.gov for a copy of the proposed forms, or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Information Relay Service at (800) 877-8339. (Other than the HUD USER information line and TTY numbers, telephone numbers are not toll-free.)

FOR FURTHER INFORMATION CONTACT: Dacia Rogers, Office of Policy, Programs and Legislative Initiatives, PIH, Department of Housing and Urban Development, 451 7th Street, SW.,

Room 4116, Washington, DC 20410; telephone 202-708-0713, (this is not a toll-free number). Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Information Relay Service at (800) 877-8339. (Other than the HUD USER information line and TTY numbers, telephone numbers are not toll-free.)

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended). This notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated collection techniques or other forms of information technology; e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Section 8 Management Assessment Program (SEMAP).

OMB Approval Number: 2577-0215.

Form Numbers: HUD-52648.

Description of the Need for the Information and its Proposed Use: Program regulations at 24 CFR part 985 set forth the requirements of the SEMAP that include a certification of indicators reflecting performance. Through this assessment, HUD can improve oversight of the Housing Choice Voucher program and target monitoring and assistance to public housing agencies (PHA) that need the most improvement and pose the greatest risk. PHAs designated as troubled must implement corrective action plans for improvements.

Members of the Affected Public: Respondents: State, Local, or Tribal Governments.

Frequency of SEMP Certification Submission: Annually.

	Number of respondents	×	Frequency of response	×	Hours per response	=	Burden hours
Reporting Burden	2,437		1		12		29,244
Corrective Action Plan	100		1		10		1,000
Report on Correction of SEMAP Deficiency	609		1		2		1,218

Total Estimated Burden Hours:
31,462.

Status: Extension of a currently approved collection.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: October 14, 2009.

Bessy Kong,

Deputy Assistant Secretary for Policy, Programs, and Legislative Initiatives.

[FR Doc. E9-25392 Filed 10-21-09; 8:45 am]

BILLING CODE 4210-67-P

INTERNATIONAL TRADE COMMISSION

[USITC SE-09-028]

Government In the Sunshine Act Meeting Notice

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: October 30, 2009 at 11 a.m.

PLACE: Room 101, 500 E Street SW., Washington, DC 20436, Telephone: (202) 205-2000.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agenda for future meetings: none.
 2. Minutes.
 3. Ratification List.
 4. Inv. Nos. 701-TA-469 and 731-TA-1168 (Preliminary) (Certain Seamless Carbon and Alloy Steel Standard, Line, and Pressure Pipe from China)—briefing and vote. (The Commission is currently scheduled to transmit its determinations to the Secretary of Commerce on or before November 2, 2009; Commissioners' opinions are currently scheduled to be transmitted to the Secretary of Commerce on or before November 9, 2009.)
 5. Outstanding action jackets: none.
- In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

By order of the Commission:

Issued: October 20, 2009.

William R. Bishop,

Hearings and Meetings Coordinator.

[FR Doc. E9-25566 Filed 10-20-09; 4:15 pm]

BILLING CODE 7020-02-P

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Pursuant to the Comprehensive Environmental Response, Compensation and Liability Act "CERCLA"

In accordance with Departmental policy, 28 CFR 50.7, notice is hereby given that a Consent Decree in *United States v. Cabot Corporation et al.*, with Cabot Corporation; Carpenter Technology Corporation; Ford Motor Company; International Flavors and Fragrances, Inc.; Johnson Matthey, Inc.; Rütgers Organics Corporation; Spectraserv, Inc., f/k/a Modern Transportation and A&S Transportation Co.; Waste Management of New Jersey, Inc.; CWM Chemical Services, LLC; and Spiral Metal Company, Inc. (hereinafter referred to as "Settling Defendants") at the Evor Phillips Leasing Superfund Site ("Site"). Civil No.3:09-cv-5263, was lodged on October 15, 2009, with the United States District Court for the District of New Jersey.

The Consent Decree resolves claims for response costs and injunctive relief against Settling Defendants, under the Sections 106, 107 and 113 of the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended, ("CERCLA"), 42 U.S.C. 9601, *et seq.* and regulations promulgated thereunder. In this action, the United States seeks injunctive relief requiring defendants to perform the response actions selected in EPA's Record of Decision ("ROD") for Operable Unit 2 ("OU2") at the Site, located on Old Waterworks Road in the Township of Old Bridge, Middlesex County, New Jersey. The United States also seeks to recover certain costs incurred or to be incurred by the United States in connection with the release or threatened release of hazardous substances into the environment at or from the Site.

Pursuant to the Consent Decree, Settling Defendants have agreed under this Consent Decree to implement the remedy selected in the OU2 ROD to address soil contamination at the Site, pay \$231,000 in past costs (96%) plus interest on all such costs which has accrued after February 2, 2009, and pay Future Response Costs.

The Department of Justice will receive, for a period of thirty (30) days from the date of this publication, comments relating to the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and either e-mailed to pubcomment-ees.enrd@usdoj.gov or mailed to P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044-7611, and should refer to *United States v. Cabot Corporation, et al.*; Civil Action No., D.J. Ref. No.90-11-3-07162/2.

The proposed Consent Decree may be examined at the Office of the United States Attorney, District of New Jersey, 970 Broad Street, Room 502, Newark, New Jersey 07102, and at the United States Environmental Protection Agency, 290 Broadway, New York, New York 10007-1866. During the public comment period, the proposed Consent Decree may also be examined on the following Department of Justice Web site, http://www.usdoj.gov/enrd/Consent_Decrees.html. A copy of the proposed Consent Decree may be obtained by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044-7611 or by faxing or e-mailing a request to Tonia Fleetwood (tonia.fleetwood@usdoj.gov), fax no. (202) 514-0097, phone confirmation number (202) 514-1547. In requesting a copy from the Consent Decree Library, please enclose a check in the amount of \$6.60 (25 cents per page reproduction cost) payable to the U.S. Treasury or, if by e-mail or fax, forward a check in that amount to the Consent Decree Library at the stated address.

Maureen Katz,

Assistant Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. E9-25354 Filed 10-21-09; 8:45 am]

BILLING CODE 4410-15-P

DEPARTMENT OF JUSTICE**Antitrust Division****Notice Pursuant to the National Cooperative Research and Production Act of 1993—LiMo Foundation**

Notice is hereby given that, on September 8, 2009, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (“the Act”), LiMo Foundation (“LiMo”) filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act’s provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Casio Hitachi Mobile Communications Co., Ltd., Tokyo, Japan; Aromasoft Corporation, Seoul, Republic of Korea; Swisscom (Schweiz) AG, Bern, Switzerland; Opera Software ASA, Oslo, Norway; and Immersion Corporation, San Jose, CA, have been added as parties to this venture.

Also, Advanced Micro Devices Inc., Markham, Ontario, Canada; Infineon Technologies AG, Neubiberg, Germany; VirtualLogix, Inc., Sunnyvale, CA; FueTrek Co., Ltd., Osaka, Japan; Innopath Software Inc., Sunnyvale, CA; Cellon Communications Technology (Shenzhen) Co., Ltd., Shenzhen, People’s Republic of China; Esmertec AG, Dubendorf, Switzerland; Freescale Semiconductor, Inc., Austin, TX; Shanghai Longcheer 3G Technology Co., Ltd., Shanghai, People’s Republic of China; MIZI Research Incorporated, Seoul, Republic of Korea; MontaVista Software, Inc., Santa Clara, CA; NXP Semiconductors B.V., Eindhoven, The Netherlands; TroilTech ASA, Oslo, Norway; and Sagem Mobiles, Cergy St Christophe Cedex, France, have withdrawn as parties to this venture.

No other changes have been made in either the membership or planned activity of this group research project. Membership in this group research project remains open, and LiMo intends to file additional written notifications disclosing all changes in membership.

On March 1, 2007, LiMo filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on April 9, 2007 (72 FR 17583).

The last notification was filed with the Department on January 5, 2009. A notice was published in the **Federal**

Register pursuant to Section 6(b) of the Act on February 26, 2009 (74 FR 8812).

Patricia A. Brink,

Deputy Director of Operations, Antitrust Division.

[FR Doc. E9–25304 Filed 10–21–09; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE**Antitrust Division****Notice Pursuant to the National Cooperative Research and****Production Act of 1993—OpenSAF Foundation**

Notice is hereby given that, on September 10, 2009, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (“the Act”), OpenSAF Foundation has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act’s provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Tail-f Systems AD, Stockholm, SWEDEN; and IP Infusion, Sunnyvale, CA have been added as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and OpenSAF Foundation intends to file additional written notifications disclosing all changes in membership.

On April 8, 2008, OpenSAF Foundation filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on May 16, 2008 (73 FR 28508).

The last notification was filed with the Department on November 6, 2008. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on December 12, 2008 (73 FR 75772).

Patricia A. Brink,

Deputy Director of Operations, Antitrust Division.

[FR Doc. E9–25302 Filed 10–21–09; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE**Antitrust Division****Notice Pursuant to the National Cooperative Research and Production Act of 1993—Advanced Media Workflow Association, Inc.**

Notice is hereby given that, on September 24, 2009, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (“the Act”), Advanced Media Workflow Association, Inc. has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act’s provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, 3T Technology Co., Ltd., Taipei, Taiwan; RadiantGrid Technologies, LLC, Kingston, WA; and Richard Eversley (individual member), Lakewood, CO have been added as parties to this venture. Also, BPI Improve, Princes Risborough, United Kingdom; and Sun Microsystems, Santa Clara, CA have withdrawn as parties to this venture.

In addition, Artesia Digital Media Group has changed its name to Open Text Media Group, Beaconsfield, United Kingdom.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and Advanced MediaWorkflow Association, Inc. intends to file additional written notifications disclosing all changes in membership.

On March 28, 2000, Advanced Media Workflow Association, Inc. filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on June 29, 2000 (65 FR 40127).

The last notification was filed with the Department on June 10, 2009. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on July 15, 2009 (74 FR 34365).

Patricia A. Brink,

Deputy Director of Operations, Antitrust Division.

[FR Doc. E9–25260 Filed 10–21–09; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE**Antitrust Division****Notice Pursuant to the National Cooperative Research and Production Act of 1993—IMS Global Learning Consortium, Inc.**

Notice is hereby given that, on September 17, 2009, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (“the Act”), IMS Global Learning Consortium, Inc. has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act’s provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Athabasca University, Athabasca, Alberta, Canada; BPS Bildungsportal Sachsen GmbH, Chemnitz, Germany; and Levelland Independent School District, Levelland, TX have been added as parties to this venture.

Also, University of North Carolina—Wilmington, Wilmington, NC; Angel Learning, Indianapolis, IN; Information Management Specialists, Montgomery, AL; eCollege.com, Denver, CO; Embanet, Toronto, Ontario, Canada; TIDIA Ae FAPESP Project, Sao Paulo, Brazil; Common Need, Inc., Alexandria, VA; and ACT, Iowa City, IA have withdrawn as parties to this venture.

In addition, Norwegian eStandards Project has changed its name to The Norwegian Secretariat for Standardization Learning Technology (NSSL), Oslo, Norway.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and IMS Global Learning Consortium, Inc. intends to file additional written notifications disclosing all changes in membership.

On April 7, 2000, IMS Global Learning Consortium, Inc. filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on September 13, 2000 (65 FR 55283)

The last notification was filed with the Department on June 30, 2009. A notice was published in the **Federal**

Register pursuant to Section 6(b) of the Act on August 21, 2009 (74 FR 42330).

Patricia A. Brink,

Deputy Director of Operations, Antitrust Division.

[FR Doc. E9–25306 Filed 10–21–09; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE**Antitrust Division****Notice Pursuant to the National Cooperative Research and Production Act of 1993—ASTM International**

Notice is hereby given that, on September 8, 2009, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (“the Act”), ASTM International (“ASTM”) has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing additions or changes to its standards development activities. The notifications were filed for the purpose of extending the Act’s provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, ASTM has provided an updated list of current, ongoing ASTM standards activities originating between May 2009 and September 2009 designated as work items. A complete listing of ASTM work items, along with a brief description of each, is available at <http://www.astm.org>.

On September 15, 2004, ASTM filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on November 10, 2004 (69 FR 65226).

The last notification was filed with the Department on May 18, 2009. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on June 15, 2009 (74 FR 28728).

Patricia A. Brink,

Deputy Director of Operations, Antitrust Division.

[FR Doc. E9–25305 Filed 10–21–09; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE**Antitrust Division****Notice Pursuant to the National Cooperative Research and Production Act of 1993—Interchangeable Virtual Instruments Foundation, Inc.**

Notice is hereby given that, on September 10, 2009, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (“the Act”), Interchangeable Virtual Instruments Foundation, Inc. has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act’s provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Nokia, Copenhagen, Denmark has been added as a party to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and Interchangeable Virtual Instruments Foundation, Inc. intends to file additional written notifications disclosing all changes in membership.

On May 29, 2001, Interchangeable Virtual Instruments Foundation, Inc. filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on July 30, 2001 (66 FR 39336).

The last notification was filed with the Department on June 22, 2009. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on August 3, 2009 (74 FR 38473).

Patricia A. Brink,

Deputy Director of Operations, Antitrust Division.

[FR Doc. E9–25303 Filed 10–21–09; 8:45 am]

BILLING CODE 4410–11–M

NUCLEAR REGULATORY COMMISSION**Advisory Committee on Reactor Safeguards**

In accordance with the purposes of Sections 29 and 182b of the Atomic Energy Act (42 U.S.C. 2039, 2232b), the Advisory Committee on Reactor Safeguards (ACRS) will hold a meeting on November 5–7, 2009, 11545 Rockville Pike, Rockville, Maryland.

The date of this meeting was previously published in the **Federal Register** on Monday, October 6, 2008, (73 FR 58268–58269).

**Thursday, November 5, 2009,
Conference Room T2–B3, Two White
Flint North, Rockville, Maryland.**

8:30 a.m.–8:35 a.m.: Opening Remarks by the ACRS Chairman (Open)—The ACRS Chairman will make opening remarks regarding the conduct of the meeting.

8:35 a.m.–10:30 a.m.: Amendments to the AP1000 Design Control Document (DCD) (Open)—The Committee will hear presentations by and hold discussions with representatives of the NRC staff and Westinghouse Electric Company regarding amendments to the AP1000 DCD and related matters.

10:45 a.m.–12:15 p.m.: Draft Final Regulatory Guide 5.71, “Cyber Security Programs for Nuclear Facilities” (Open/Closed)—The Committee will hear presentations by and hold discussions with representatives of the NRC staff regarding draft final Regulatory Guide 5.71, “Cyber Security Programs for Nuclear Facilities,” NRC staff’s resolution of public comments, and related matters. [Note: A portion of this session may be closed to discuss and protect information classified as National Security Information as well as Safeguards Information pursuant to 5 U.S.C. 552b (c) (1) and (3).]

1:15 p.m.–3:15 p.m.: Overview of the Advanced Boiling Water Reactor (ABWR) Design as Applied to the South Texas Project (STP) Combined License Application (COLA) (Open/Closed)—The Committee will hear presentations by and hold discussions with representatives of the NRC staff and the STP Nuclear Operating Company regarding an overview of the ABWR design as it applies to the STP COLA and related matters. [Note: A portion of this session may be closed to discuss and protect information classified as National Security Information as well as Safeguards Information pursuant to 5 U.S.C. 552b (c) (1) and (3).]

3:30 p.m.–5:30 p.m.: NRC Staff’s Plan for the STP COLA Review (Open)—The Committee will hear presentations by and hold discussions with representatives of the NRC staff regarding staff’s plan for reviewing the STP COLA and related matters.

5:45 p.m.–7 p.m.: Preparation of ACRS Reports (Open)—The Committee will discuss proposed ACRS reports on matters discussed during this meeting.

**Friday, November 6, 2009, Conference
Room T2–B3, Two White Flint North,
Rockville, Maryland.**

8:30 a.m.–8:35 a.m.: Opening Remarks by the ACRS Chairman (Open)—The ACRS Chairman will make opening remarks regarding the conduct of the meeting.

8:35 a.m.–10 a.m.: Future ACRS Activities/Report of the Planning and Procedures Subcommittee (Open/Closed)—The Committee will discuss the recommendations of the Planning and Procedures Subcommittee regarding items proposed for consideration by the Full Committee during future ACRS meetings, including anticipated workload and member assignments, review of applications for membership, and related matters. [Note: A portion of this session may be closed pursuant to 5 U.S.C. 552b (c)(2) and (6) to discuss organizational and personnel matters that relate solely to internal personnel rules and practices of ACRS, and information the release of which would constitute a clearly unwarranted invasion of personal privacy.]

10 a.m.–10:15 a.m.: Reconciliation of ACRS Comments and Recommendations (Open)—The Committee will discuss the responses from the NRC Executive Director for Operations to comments and recommendations included in recent ACRS reports and letters.

10:30 a.m.–12 p.m.: Preparation for Meeting with the Commission on December 4, 2009 (Open)—The Committee will discuss topics for its meeting with the Commission on December 4, 2009.

1 p.m.–3:30 p.m.: Draft ACRS Report on the NRC Safety Research Program (Open)—The Committee will discuss the draft ACRS report on the NRC Safety Research Program.

3:45 p.m.–4:45 p.m.: Significant Operating Experience (Open)—The Committee will hear a report by and hold discussions with the Chairman of the ACRS Subcommittee on Plant Operations and Fire Protection regarding significant operating events, insights gained from these events, and any follow-up actions by the Subcommittee and/or the Full Committee.

4:45 p.m.–5:15 p.m.: Subcommittee Reports (Open)—The Committee will hear reports by and hold discussions with the Chairmen of the ACRS Subcommittees regarding: Resolution of Open Items associated with the review of the ESBWR Design Certification; the Evolutionary Power Reactor (EPR) Design Certification Application Review; and the NUREG–1520,

“Standard Review Plan for Review of a License Application for a Fuel Cycle Facility,” that were discussed during the meetings on October 20–22, November 3, and 4, 2009, respectively.

5:30 p.m.–7 p.m.: Preparation of ACRS Reports (Open)—The Committee will discuss proposed ACRS reports.

**Saturday, November 7, 2009,
Conference Room T2–B3, Two White
Flint North, Rockville, Maryland**

8:30 a.m.–10 a.m.: Preparation of ACRS Reports (Open)—The Committee will continue its discussion of proposed ACRS reports.

10:15 a.m.–1 p.m.: Process for ACRS Review of Amendments to the DCD of Previously Certified Reactor Designs (Open)—The Committee will discuss potential enhancements to the current ACRS process for reviewing amendments to the DCDs related to previously certified reactor designs.

1 p.m.–1:30 p.m.: Miscellaneous (Open)—The Committee will continue its discussion related to the conduct of Committee activities and specific issues that were not completed during previous meetings.

Procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 14, 2009, (74 FR 52829–52830). In accordance with those procedures, oral or written views may be presented by members of the public, including representatives of the nuclear industry. Thirty-five hard copies of each presentation or handout should be provided to the Designated Federal Official 30 minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the Designated Federal Official one day before the meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the Designated Federal Official with a CD containing each presentation at least 30 minutes before the meeting. Electronic recordings will be permitted only during the open portions of the meeting. Persons desiring to make oral statements should notify the Cognizant ACRS staff named below five days before the meeting, if possible, so that appropriate arrangements can be made to allow necessary time during the meeting for such statements. Use of still, motion picture, and television cameras during the meeting may be limited to selected portions of the meeting as determined by the Chairman. Information regarding the time to be set aside for this purpose may be obtained by contacting the Cognizant ACRS staff prior to the meeting. In view of the possibility that the schedule for ACRS

meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with the Cognizant ACRS staff if such rescheduling would result in major inconvenience.

In accordance with Subsection 10(d) Public Law 92-463, I have determined that it may be necessary to close a portion of this meeting noted above to discuss organizational and personnel matters that relate solely to internal personnel rules and practices of ACRS, and information the release of which constitute a clearly unwarranted invasion of personal privacy pursuant to 5 U.S.C. 552b(c)(2) and (6). In addition it may be necessary to close portion of the meeting to protect information classified as national security, as well as safeguards information pursuant to 5 U.S.C. 552b(c)(1),(2) and (3).

Further information regarding topics to be discussed, whether the meeting has been canceled or rescheduled, as well as the Chairman's ruling on requests for the opportunity to present oral statements and the time allotted therefor can be obtained by contacting Girija Shukla, Cognizant ACRS staff (301-415-6855), between 7:15 a.m. and 5 p.m. (ET). ACRS meeting agenda, meeting transcripts, and letter reports are available through the NRC Public Document Room at pdr.resource@nrc.gov, or by calling the PDR at 1-800-397-4209, or from the Publicly Available Records System (PARS) component of NRC's document system (ADAMS) which is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> or <http://www.nrc.gov/reading-rm/doc-collections/ACRS/>.

Video teleconferencing service is available for observing open sessions of ACRS meetings. Those wishing to use this service for observing ACRS meetings should contact

Mr. Theron Brown, ACRS Audio Visual Technician (301-415-8066), between 7:30 a.m. and 3:45 p.m., (ET), at least 10 days before the meeting to ensure the availability of this service.

Individuals or organizations requesting this service will be responsible for telephone line charges and for providing the equipment and facilities that they use to establish the video teleconferencing link. The availability of video teleconferencing services is not guaranteed.

Dated: October 15, 2009.

Andrew L. Bates,

Advisory Committee Management Officer.

[FR Doc. E9-25320 Filed 10-21-09; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS); Meeting of the ACRS Subcommittee on ESBWR; Notice of Meeting

The ACRS Subcommittee on the Economic Simplified Boiling Water Reactor (ESBWR) will hold a meeting on November 17-18, 2009, Room T2-B3, 11545 Rockville Pike, Rockville, Maryland.

The meeting will be open to public attendance, with the exception of a portion that may be closed to protect information that is proprietary to General Electric—Hitachi Nuclear Americas, LLC (GEH) and its contractors pursuant to 5 U.S.C. 552b(c)(4).

The agenda for the subject meeting shall be as follows:

Tuesday, November 17, 2009, 8:30 a.m.–5 p.m.

Wednesday, November 18, 2009, 8:30 a.m.–1 p.m.

The Subcommittee will review the resolution of containment issues and ventilation and dose issues associated with the ESBWR design certification. The Subcommittee will hear presentations by and hold discussions with representatives of the NRC staff, GEH, and other interested persons regarding this matter.

The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official (DFO), Christopher L. Brown (Telephone: 301-415-7111, E-mail: Christopher.Brown@nrc.gov) five days prior to the meeting, if possible, so that appropriate arrangements can be made. Thirty-five hard copies of each presentation or handout should be provided to the DFO thirty minutes before the meeting. In addition, one electronic copy of each presentation should be e-mailed to the DFO one day before the meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the DFO with a CD containing each presentation at least 30 minutes before the meeting. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 14, 2009 (74 FR 52829-52830).

Detailed meeting agendas and meeting transcripts are available on the NRC Web site at <http://www.nrc.gov/reading-rm/doc-collections/acrs>. Information regarding topics to be discussed, changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained from the Web site cited above or by contacting the identified DFO. Moreover, in view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with these references if such rescheduling would result in major inconvenience.

Dated: October 15, 2009.

Cayetano Santos,

Chief, Reactor Safety Branch A, Advisory Committee on Reactor Safeguards.

[FR Doc. E9-25423 Filed 10-21-09; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards; Meeting of the ACRS Subcommittee on Reliability and Probabilistic Risk Assessment; Notice of Meeting

The ACRS Subcommittee on Reliability and Probabilistic Risk Assessment (PRA) will hold a meeting on November 13, 2009, in Room T2-B3, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland.

The entire meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

Friday, November 13, 2009–8:30 a.m.–2:30 p.m.

The Subcommittee will review the Draft Final Revision 1 to Regulatory Guide 1.205 (DG-1218), "Risk-Informed, Performance-Based Fire Protection for Existing Light-Water Nuclear Power Plants;" the Draft final Standard Review Plan Section 9.5.1.2, "Risk-Informed and Performance-Based Fire Protection Program;" NRC Staff's resolution of public comments on these documents; and related matters. The Subcommittee will hear presentations by and hold discussions with representatives of the NRC staff, the Nuclear Energy Institute, the Electric Power Research Institute, and other interested persons regarding these matters. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as

appropriate, for deliberation by the full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official (DFO), Girija S. Shukla (Telephone: 301-415-6855, E-mail: Girija.Shukla@nrc.gov), five days prior to the meeting, if possible, so that appropriate arrangements can be made. Thirty-five hard copies of each presentation or handout should be provided to the DFO thirty minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the DFO one day before the meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the DFO with a CD containing each presentation at least 30 minutes before the meeting. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 14, 2009, (74 FR 52829-52830).

Detailed meeting agendas and meeting transcripts are available on the NRC Web site at <http://www.nrc.gov/reading-rm/doc-collections/acrs>. Information regarding topics to be discussed, changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained from the website cited above or by contacting the identified DFO. Moreover, in view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with these references if such rescheduling would result in major inconvenience.

Dated: October 15, 2009.

Yaira Diaz-Sanabria,

*Acting Chief, Reactor Safety Branch B,
Advisory Committee on Reactor Safeguards.*
[FR Doc. E9-25421 Filed 10-21-09; 8:45 am]
BILLING CODE 7590-01-P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC 2010-2 and CP2010-2;
Order No. 315]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recently-filed Postal Service request to add Priority Mail Contract 2- to the

Competitive Product List. The Postal Service has also filed a related contract. This notice addresses procedural steps associated with these filings.

DATES: Comments are due October 26, 2009.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at <http://www.prc.gov>.

FOR FURTHER INFORMATION CONTACT:

Stephen L. Sharfman, General Counsel, 202-789-6820 and stephen.sharfman@prc.gov.

SUPPLEMENTARY INFORMATION:

- I. Introduction
- II. Notice of Filing
- III. Ordering Paragraphs

I. Introduction

On October 14, 2009, the Postal Service filed a formal request pursuant to 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.* to add Priority Mail Contract 20 to the Competitive Product List.¹ The Postal Service asserts that Priority Mail Contract 20 is a competitive product "not of general applicability" within the meaning of 39 U.S.C. 3632(b)(3). The Postal Service states that prices and classification underlying this contract are supported by Governors' Decision No. 09-6 in Docket No. MC2009-25. *Id.* at 1. The Request has been assigned Docket No. MC2010-2.

The Postal Service contemporaneously filed a contract related to the proposed new product pursuant to 39 U.S.C. 3632(b)(3) and 39 CFR 3015.5. The contract has been assigned Docket No. CP2010-2.

Request. In support of its Request, the Postal Service filed the following materials: (1) A redacted version of the Governors' Decision, originally filed in Docket No MC2009-25, authorizing certain Priority Mail contracts;² (2) a redacted version of the contract;³ (3) a requested change in the Competitive Product List;⁴ (4) a Statement of Supporting Justification as required by 39 CFR 3020.32;⁵ (5) a certification of compliance with 39 U.S.C. 3633(a);⁶ and (6) an application for non-public treatment of the materials filed under seal.⁷

¹ Request of the United States Postal Service to Add Priority Mail Contract 20 to Competitive Product List and Notice of Filing (Under Seal) of Contract and Supporting Data, October 14, 2009 (Request).

² Attachment A to the Request, reflecting Governors' Decision No. 09-6, April 27, 2009.

³ Attachment B to the Request.

⁴ Attachment C to the Request.

⁵ Attachment D to the Request.

⁶ Attachment E to the Request.

⁷ Attachment F to the Request.

In the Statement of Supporting Justification, Mary Prince Anderson, Acting Manager, Sales and Communications, Expedited Shipping, asserts that the service to be provided under the contract will cover its attributable costs, make a positive contribution to institutional costs, and increase contribution toward the requisite 5.5 percent of the Postal Service's total institutional costs. *Id.*, Attachment D. Thus, Ms. Anderson contends there will be no issue of subsidization of competitive products by market dominant products as a result of this contract. *Id.*

Related contract. A redacted version of the specific Priority Mail Contract 20 is included with the Request. The contract will become effective on the day that the Commission provides all necessary regulatory approvals. It is terminable upon 30 days' notice by a party, but could continue for 3 years with annual adjustments. The Postal Service represents that the contract is consistent with 39 U.S.C. 3633(a)(1). *See id.*, Attachment D. The Postal Service will provide the shipper with Priority Mail packaging for eligible Priority Mail items mailed by the shipper.

The Postal Service filed much of the supporting materials, including the specific Priority Mail Contract 20, under seal. In its Request, the Postal Service maintains that the contract and related financial information, including the customer's name and the accompanying analyses that provide prices, terms, conditions, cost data, and financial projections should remain under seal. *Id.* at 2. It also requests that the Commission order that the duration of such treatment of all customer identifying information be extended indefinitely, instead of ending after 10 years. *Id.*, Attachment F at 1 and 7.

II. Notice of Filings

The Commission establishes Docket Nos. MC2010-2 and CP2010-2 for consideration of the Request pertaining to the proposed Priority Mail Contract 20 product and the related contract, respectively. In keeping with practice, these dockets are addressed on a consolidated basis for purposes of this order; however, future filings should be made in the specific docket in which issues being addressed pertain.

Interested persons may submit comments on whether the Postal Service's filings in the captioned dockets are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642 and 39 CFR part 3015 and 39 CFR 3020 subpart B. Comments are due no later than October 26, 2009. The public portions of these filings can be accessed via the

Commission's Web site (<http://www.prc.gov>).

The Commission appoints Paul L. Harrington to serve as Public Representative in these dockets.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket Nos. MC2010-2 and CP2010-2 for consideration of the matter raised in each docket.

2. Pursuant to 39 U.S.C. 505, Paul L. Harrington is appointed to serve as officer of the Commission (Public Representative) to represent the interests of the general public in these proceedings.

3. Comments by interested persons in these proceedings are due no later than October 26, 2009.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Shoshana M. Grove,
Secretary.

[FR Doc. E9-25473 Filed 10-21-09; 8:45 am]

BILLING CODE 7710-FW-P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2010-3 and CP2010-3;
Order No. 316]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recently-filed Postal Service request to add Priority Mail Contract 21 to the Competitive Product List. The Postal Service has also filed a related contract. This notice addresses procedural steps associated with these filings.

DATES: Comments are due October 26, 2009.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at <http://www.prc.gov>.

FOR FURTHER INFORMATION CONTACT:

Stephen L. Sharfman, General Counsel, 202-789-6820 and stephen.sharfman@prc.gov.

SUPPLEMENTARY INFORMATION:

- I. Introduction
- II. Notice of Filings
- III. Ordering Paragraphs

I. Introduction

On October 14, 2009, the Postal Service filed a formal request pursuant to 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.* to add Priority Mail Contract 21

to the Competitive Product List.¹ The Postal Service asserts that Priority Mail Contract 21 is a competitive product "not of general applicability" within the meaning of 39 U.S.C. 3632(b)(3). The Postal Service states that prices and classification underlying this contract are supported by Governors' Decision No. 09-6 in Docket No. MC2009-25. *Id.* at 1. The Request has been assigned Docket No. MC2010-3.

The Postal Service contemporaneously filed a contract related to the proposed new product pursuant to 39 U.S.C. 3632(b)(3) and 39 CFR 3015.5. The contract has been assigned Docket No. CP2010-3.

Request. In support of its Request, the Postal Service filed the following materials: (1) A redacted version of the Governors' Decision, originally filed in Docket No MC2009-25, authorizing certain Priority Mail contracts;² (2) a redacted version of the contract;³ (3) a requested change in the Competitive Product List;⁴ (4) a Statement of Supporting Justification as required by 39 CFR 3020.32;⁵ (5) a certification of compliance with 39 U.S.C. 3633(a);⁶ and (6) an application for non-public treatment of the materials filed under seal.⁷

In the Statement of Supporting Justification, Mary Prince Anderson, Acting Manager, Sales and Communications, Expedited Shipping, asserts that the service to be provided under the contract will cover its attributable costs, make a positive contribution to institutional costs, and increase contribution toward the requisite 5.5 percent of the Postal Service's total institutional costs. *Id.*, Attachment D. Thus, Ms. Anderson contends there will be no issue of subsidization of competitive products by market dominant products as a result of this contract. *Id.*

Related contract. A redacted version of the specific Priority Mail Contract 21 is included with the Request. The contract will become effective on the day that the Commission provides all necessary regulatory approvals. It is terminable upon 30 days' notice by a party, but could continue for 3 years with annual adjustments. The Postal

Service represents that the contract is consistent with 39 U.S.C. 3633(a)(1). *See id.*, Attachment D. The Postal Service will provide the shipper with Priority Mail packaging for eligible Priority Mail items mailed by the shipper.

The Postal Service filed much of the supporting materials, including the specific Priority Mail Contract 21, under seal. In its Request, the Postal Service maintains that the contract and related financial information, including the customer's name and the accompanying analyses that provide prices, terms, conditions, cost data, and financial projections should remain under seal. *Id.* at 2. It also requests that the Commission order that the duration of such treatment of all customer identifying information be extended indefinitely, instead of ending after 10 years. *Id.*, Attachment F at 1 and 7.

II. Notice of Filings

The Commission establishes Docket Nos. MC2010-3 and CP2010-3 for consideration of the Request pertaining to the proposed Priority Mail Contract 21 product and the related contract, respectively. In keeping with practice, these dockets are addressed on a consolidated basis for purposes of this order; however, future filings should be made in the specific docket in which issues being addressed pertain.

Interested persons may submit comments on whether the Postal Service's filings in the captioned dockets are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642 and 39 CFR part 3015 and 39 CFR 3020 subpart B. Comments are due no later than October 26, 2009. The public portions of these filings can be accessed via the Commission's Web site (<http://www.prc.gov>).

The Commission appoints Paul L. Harrington to serve as Public Representative in these dockets.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket Nos. MC2010-3 and CP2010-3 for consideration of the matter raised in each docket.

2. Pursuant to 39 U.S.C. 505, Paul L. Harrington is appointed to serve as officer of the Commission (Public Representative) to represent the interests of the general public in these proceedings.

3. Comments by interested persons in these proceedings are due no later than October 26, 2009.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

¹ Request of the United States Postal Service to Add Priority Mail Contract 21 to Competitive Product List and Notice of Filing (Under Seal) of Contract and Supporting Data, October 14, 2009 (Request).

² Attachment A to the Request, reflecting Governors' Decision No. 09-6, April 27, 2009.

³ Attachment B to the Request.

⁴ Attachment C to the Request.

⁵ Attachment D to the Request.

⁶ Attachment E to the Request.

⁷ Attachment F to the Request.

By the Commission.

Shoshana M. Grove,

Secretary.

[FR Doc. E9-25474 Filed 10-21-09; 8:45 am]

BILLING CODE 7710-FW-P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2010-4 and CP2010-4;
Order No. 317]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recently-filed Postal Service request to add Priority Mail Contract 22 to the Competitive Product List. The Postal Service has also filed a related contract. This notice addresses procedural steps associated with these filings.

DATES: Postal Service response to supplemental information due October 20, 2009. Comments are due October 26, 2009.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at <http://www.prc.gov>.

FOR FURTHER INFORMATION CONTACT:

Stephen L. Sharfman, General Counsel, 202-789-6820 and stephen.sharfman@prc.gov.

SUPPLEMENTARY INFORMATION:

- I. Introduction
- II. Notice of Filings
- III. Supplemental Information
- IV. Ordering Paragraphs

I. Introduction

On October 14, 2009, the Postal Service filed a formal request pursuant to 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.* to add Priority Mail Contract 22 to the Competitive Product List.¹ The Postal Service asserts that Priority Mail Contract 22 is a competitive product "not of general applicability" within the meaning of 39 U.S.C. 3632(b)(3). The Postal Service states that prices and classification underlying this contract are supported by Governors' Decision No. 09-6 in Docket No. MC2009-25. *Id.* at 1. The Request has been assigned Docket No. MC2010-4.

The Postal Service contemporaneously filed a contract related to the proposed new product pursuant to 39 U.S.C. 3632(b)(3) and 39 CFR 3015.5. The contract has been assigned Docket No. CP2010-4.

¹ Request of the United States Postal Service to Add Priority Mail Contract 22 to Competitive Product List and Notice of Filing (Under Seal) of Contract and Supporting Data, October 14, 2009 (Request).

Request. In support of its Request, the Postal Service filed the following materials: (1) A redacted version of the Governors' Decision, originally filed in Docket No MC2009-25, authorizing certain Priority Mail contracts;² (2) a redacted version of the contract;³ (3) a requested change in the Competitive Product List;⁴ (4) a Statement of Supporting Justification as required by 39 CFR 3020.32;⁵ (5) a certification of compliance with 39 U.S.C. 3633(a);⁶ and (6) an application for non-public treatment of the materials filed under seal.⁷

In the Statement of Supporting Justification, Mary Prince Anderson, Acting Manager, Sales and Communications, Expedited Shipping, asserts that the service to be provided under the contract will cover its attributable costs, make a positive contribution to institutional costs, and increase contribution toward the requisite 5.5 percent of the Postal Service's total institutional costs. *Id.*, Attachment D. Thus, Ms. Anderson contends there will be no issue of subsidization of competitive products by market dominant products as a result of this contract. *Id.*

Related contract. A redacted version of the specific Priority Mail Contract 22 is included with the Request. The contract will become effective on the day that the Commission provides all necessary regulatory approvals. It is terminable upon 30 days' notice by a party, but could continue for 3 years with annual adjustments. The Postal Service represents that the contract is consistent with 39 U.S.C. 3633(a)(1). *See id.*, Attachment D. The Postal Service will provide the shipper with Priority Mail packaging for eligible Priority Mail items mailed by the shipper.

The Postal Service filed much of the supporting materials, including the specific Priority Mail Contract 22, under seal. In its Request, the Postal Service maintains that the contract and related financial information, including the customer's name and the accompanying analyses that provide prices, terms, conditions, cost data, and financial projections should remain under seal. *Id.* at 2. It also requests that the Commission order that the duration of such treatment of all customer identifying information be extended

² Attachment A to the Request, reflecting Governors' Decision No. 09-6, April 27, 2009.

³ Attachment B to the Request.

⁴ Attachment C to the Request.

⁵ Attachment D to the Request.

⁶ Attachment E to the Request.

⁷ Attachment F to the Request.

indefinitely, instead of ending after 10 years. *Id.*, Attachment F at 1 and 7.

II. Notice of Filings

The Commission establishes Docket Nos. MC2010-4 and CP2010-4 for consideration of the Request pertaining to the proposed Priority Mail Contract 22 product and the related contract, respectively. In keeping with practice, these dockets are addressed on a consolidated basis for purposes of this order; however, future filings should be made in the specific docket in which issues being addressed pertain.

Interested persons may submit comments on whether the Postal Service's filings in the captioned dockets are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642 and 39 CFR part 3015 and 39 CFR 3020 subpart B. Comments are due no later than October 26, 2009. The public portions of these filings can be accessed via the Commission's Web site (<http://www.prc.gov>).

The Commission appoints Paul L. Harrington to serve as Public Representative in these dockets.

III. Supplemental Information

The Commission requests the Postal Service to provide the following supplemental information regarding the new agreement by October 20, 2009: On page 3 of Attachment F to the Request, the Postal Service references redacted financial workpapers. However, no redacted workpapers were filed in support of this docket. Please provide these workpapers.

IV. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket Nos. MC2010-4 and CP2010-4 for consideration of the matter raised in each docket.

2. Pursuant to 39 U.S.C. 505, Paul L. Harrington is appointed to serve as officer of the Commission (Public Representative) to represent the interests of the general public in these proceedings.

3. Comments by interested persons in these proceedings are due no later than October 26, 2009.

4. A response to the supplemental information request is due by October 20, 2009.

5. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Shoshana M. Grove,

Secretary.

[FR Doc. E9-25477 Filed 10-21-09; 8:45 am]

BILLING CODE 7710-FW-P

SMALL BUSINESS ADMINISTRATION**[Disaster Declaration #11888 and #11889]****Georgia Disaster Number GA-00028****AGENCY:** U.S. Small Business Administration.**ACTION:** Amendment 3.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of Georgia (FEMA-1858-DR), dated 09/26/2009.

Incident: Severe Storms and Flooding.
Incident Period: 09/18/2009 through 10/08/2009.

Effective Date: 10/08/2009.

Physical Loan Application Deadline Date: 11/25/2009.

Economic Injury (EIDL) Loan Application Deadline Date: 06/28/2010.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for Private Non-Profit organizations in the State of Georgia, dated 09/26/2009, is hereby amended to establish the incident period for this disaster as beginning 09/18/2009 and continuing through 10/08/2009.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

James E. Rivera,

Acting Associate Administrator for Disaster Assistance.

[FR Doc. E9-25417 Filed 10-21-09; 8:45 am]

BILLING CODE 8025-01-P

SMALL BUSINESS ADMINISTRATION**[Disaster Declaration #11886 and #11887]****Georgia Disaster Number GA-00027****AGENCY:** U.S. Small Business Administration.**ACTION:** Amendment 3.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the State of Georgia (FEMA-1858-DR), dated 09/24/2009.

Incident: Severe Storms and Flooding.
Incident Period: 09/18/2009 and continuing through 10/08/2009.

Effective Date: 10/08/2009.

Physical Loan Application Deadline

Date: 11/23/2009.

EIDL Loan Application Deadline Date: 06/24/2010.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for the State of Georgia, dated 09/24/2009 is hereby amended to establish the incident period for this disaster as beginning 09/18/2009 and continuing through 10/08/2009.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

James E. Rivera,

Acting Associate Administrator for Disaster Assistance.

[FR Doc. E9-25418 Filed 10-21-09; 8:45 am]

BILLING CODE 8025-01-P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 28947; File No. 812-13432-02]

Pioneer Diversified High Income Trust, et al.; Notice of Application

October 16, 2009.

AGENCY: Securities and Exchange Commission ("Commission").

ACTION: Notice of application under section 6(c) of the Investment Company Act of 1940 ("Act") for an exemption from section 19(b) of the Act and rule 19b-1 under the Act.

SUMMARY OF APPLICATION: Applicants request an order to permit certain closed-end investment companies to make periodic distributions of long-term capital gains with respect to their outstanding common stock as frequently as monthly in any one taxable year, and as frequently as distributions are specified by or in accordance with the terms of any outstanding preferred stock that such investment companies may issue.

APPLICANTS: Pioneer Diversified High Income Trust, Pioneer Floating Rate Trust, Pioneer High Income Trust (collectively, the "Current Funds") and

Pioneer Investment Management, Inc. ("PIM").

DATES: *Filing Dates:* The application was filed on October 2, 2007 and amended on October 31, 2008, June 4, 2009 and October 14, 2009.

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 November 9, 2009 and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549-1090; Applicants, PIM, 60 State Street, Boston, Massachusetts 02109-1820.

FOR FURTHER INFORMATION CONTACT: Laura J. Riegel, Senior Counsel, at (202) 551-6873, or Marilyn Mann, Branch Chief, at (202) 551-6821 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or for an applicant using the Company name box, at <http://www.sec.gov/search/search.htm>, or by calling (202) 551-8090.

Applicants' Representations

1. Each Current Fund is a registered closed-end management investment company organized as a Delaware statutory trust. Each Current Fund (other than Pioneer Diversified High Income Trust) has outstanding one class of common stock and three series of preferred stock. Pioneer Diversified High Income Trust has outstanding one class of common stock. Applicants believe that the shareholders of the Current Funds may prefer an investment vehicle that provides regular/monthly distributions and a steady cash flow through a fixed distribution policy. Applicants request that the order apply to any registered closed-end investment company that in the future is advised by PIM (including any successor in

interest)¹ or by an entity controlling, controlled by, or under common control (within the meaning of section 2(a)(9) of the Act) with PIM (any such entity or PIM, the "Investment Adviser") (such investment companies, the "Future Funds," and together with the Current Funds, the "Funds").²

2. PIM is registered as an investment adviser under the Investment Advisers Act of 1940. PIM is an indirect wholly-owned subsidiary of UniCredit S.p.A, an Italian banking company and global services organization.

3. Applicants represent that prior to relying on the requested order, the board of trustees (the "Board") of a Fund, including a majority of the Board members who are not "interested persons" of such Fund as defined in section 2(a)(19) of the Act (the "Independent Trustees"), shall have requested and considered, and the Investment Adviser shall have provided, information regarding the purpose and terms of a proposed distribution policy, the likely effects of such distribution policy on the Fund's long-term total return (in relation to market price and net asset value ("NAV") per common share) and the relationship between the Fund's distribution rate on its common shares under the distribution policy and the Fund's total return (in relation to NAV per share). Applicants state that the Independent Trustees of each Fund also shall have considered what conflicts of interest the Investment Adviser and the affiliated persons of the Investment Adviser and each Fund might have with respect to the adoption or implementation of such distribution policy. Applicants further state that after considering such information the Board, including the Independent Trustees, of each Fund shall approve a distribution policy with respect to each Fund's common shares (a "Plan") and shall determine that Plan is consistent with the relevant Fund's investment objectives and in the best interests of such Fund's common shareholders.

4. Applicants state that the purpose of each Plan would be to permit a Fund to distribute, over the course of each year, through periodic distributions as nearly equal as practicable and any required special distributions, an amount closely approximating the total taxable income

of the Fund during such year and, if so determined by its Board, all or a portion of the returns of capital paid by portfolio companies to the Fund during such year. Applicants represent that the Fund would distribute to its common shareholders a fixed monthly percentage of the market price of the Fund's common shares at a particular point in time or a fixed monthly percentage of NAV at particular time or a fixed monthly amount under the Plan, any of which percentage or amount may be adjusted from time to time. Applicants state that the minimum annual distribution rate with respect to a Fund's common shares under each Plan would be independent of the Fund's performance during any particular period but would be expected to correlate with the Fund's performance over time. Applicants explain that each distribution on the common stock would be at the stated rate then in effect, except for extraordinary distributions and potential increases or decreases in the final distribution periods in light of the Fund's performance for the entire calendar year and to enable the Fund to comply with the distribution requirements of subchapter M of the Internal Revenue Code of 1986 (the "Code") for the calendar year. Applicants expect that over time the distributions with respect to a Fund's common shares would correlate with that Fund's total return plus, if applicable, distributions of capital received from such Fund's portfolio companies.

5. Applicants represent that, prior to the implementation of a Plan, the Board of each Fund shall adopt policies and procedures under rule 38a-1 under the Act that are reasonably designed to ensure that all notices sent to shareholders with distributions under the Plan (each, a "19(a) Notice") include the disclosure required by rule 19a-1 and by condition 2(a) below, and that all other written communications by a Fund or its agents regarding distributions under the Plan include the disclosure required by condition 3(a) below. Applicants state that the Board of each Fund also will adopt policies and procedures that require the Fund to keep records that demonstrate the Fund's compliance with all of the terms and conditions of the requested order and that are necessary for each Fund to form the basis for, or demonstrate the calculation of, the amounts disclosed in its 19(a) Notices.

Applicants' Legal Analysis

1. Section 19(b) generally makes it unlawful for any registered investment company to make long-term capital

gains distributions more than once each year. Rule 19b-1 limits the number of capital gains dividends, as defined in section 852(b)(3)(C) of the Code ("distributions"), that a fund may make with respect to any one taxable year to one, plus a supplemental "clean up" distribution made pursuant to section 855 of the Code not exceeding 10% of the total amount distributed for the year, plus one additional capital gain dividend made in whole or in part to avoid the excise tax under section 4982 of the Code.

2. Section 6(c) provides that the Commission may, by order upon application, conditionally or unconditionally exempt any person, security, or transaction, or any class or classes of persons, securities or transactions, from any provision of the Act or of any rule under the Act, if and to the extent that the 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.

3. Applicants state that one of the concerns underlying section 19(b) and rule 19b-1 is that shareholders might be unable to distinguish between regular distributions of capital gains and dividends from investment income. Applicants state, however, that rule 19a-1 effectively addresses this concern by requiring that a separate statement showing the sources of a distribution (e.g., estimated net income, net short-term capital gains, net long-term capital gains and/or return of capital) accompany any distributions (or the confirmation of the reinvestment of distributions) estimated to be sourced in part from capital gains or capital. Applicants state that the same information is included in each Current Fund's annual report to shareholders and on its IRS Form 1099-DIV, which is sent to each common and preferred shareholder who received distributions during a particular year.

4. Applicants further state that each Fund will make the additional disclosures required by the conditions set forth below, and each of them will adopt compliance policies and procedures in accordance with rule 38a-1 to ensure that all required notices and disclosures are sent to shareholders. Applicants argue that by providing the information required by section 19(a) and rule 19a-1, the Plan, and the compliance policies and procedures in accordance with rule 38-1, each Fund will ensure that the Fund's shareholders are provided sufficient information to understand that their periodic distributions are not tied to the Fund's

¹ A successor in interest is limited to entities that result from a reorganization into another jurisdiction or a change in the type of business organization.

² All existing registered closed-end investment companies that currently intend to rely on the requested order are named as applicants. Any Future Fund that relies on the order in the future will comply with the terms and conditions of the order.

net investment income (which for this purpose is the Fund's taxable income other than from capital gains) and realized capital gains to date, and may not represent yield or investment return. Applicants also state that compliance with each Fund's compliance procedures and condition 3 set forth below will ensure that prospective shareholders and third parties are provided with the same information. Accordingly, applicants assert that continuing to subject the Funds to section 19(b) and rule 19b-1 would afford shareholders no extra protection.

5. Applicants note that section 19(b) and rule 19b-1 also were intended to prevent certain improper sales practices including, in particular, the practice of urging an investor to purchase shares of a fund on the basis of an upcoming capital gains dividend ("selling the dividend"), where the dividend would result in an immediate corresponding reduction in NAV and would be in effect a taxable return of the investor's capital. Applicants assert that the "selling the dividend" concern should not apply to closed-end investment companies, such as the Funds, which do not continuously distribute shares. According to applicants, if the underlying concern extends to secondary market purchases of shares of closed-end funds that are subject to a large upcoming capital gains distribution, adoption of a periodic distribution plan actually helps minimize the concern by avoiding, through periodic distributions, any buildup of large end-of-the-year distributions.

6. Applicants also note that common shares of closed-end funds often trade in the marketplace at a discount to the funds' NAV. Applicants believe that this discount may be reduced for the Funds if they are permitted to pay relatively frequent dividends on their common shares at a consistent rate, whether or not those dividends contain an element of capital gain.

7. Applicants assert that the application of rule 19b-1 to a Plan actually could have an undesirable influence on portfolio management decisions. Applicants state that, in the absence of an exemption from rule 19b-1, the implementation of a periodic distribution plan imposes pressure on management (i) not to realize any net long-term capital gains until the point in the year that the fund can pay all of its remaining distributions in accordance with rule 19b-1, and (ii) not to realize any long-term capital gains during any particular year in excess of the amount of the aggregate pay-out for the year (since as a practical matter excess gains

must be distributed and accordingly would not be available to satisfy pay-out requirements in following years), notwithstanding that purely investment considerations might favor realization of long-term gains at different times or in different amounts. Applicants thus assert that the limitation on the number of capital gains distributions that a fund may make with respect to any one year imposed by rule 19b-1, may prevent the efficient operation of a periodic distribution plan whenever that fund's realized net long-term capital gains in any year exceed the total of the periodic distributions that may include such capital gains under the rule.

8. In addition, applicants assert that rule 19b-1 may cause fixed regular periodic distributions under a periodic distribution plan to be funded with returns of capital³ (to the extent net investment income and realized short-term capital gains are insufficient to fund the distribution), even though realized net long-term capital gains otherwise could be available. To distribute all of a Fund's long-term capital gains within the limits in rule 19b-1, a Fund may be required to make total distributions in excess of the annual amount called for by its Plan, or to retain and pay taxes on the excess amount. Applicants thus assert that the requested order would minimize these effects of rule 19b-1 by enabling the Funds to realize long-term capital gains as often as investment considerations dictate without fear of violating rule 19b-1.

9. Applicants state that Revenue Ruling 89-81 under the Code requires that a fund that has both common stock and preferred stock outstanding designate the types of income, e.g., investment income and capital gains, in the same proportion as the total distributions distributed to each class for the tax year. To satisfy the proportionate designation requirements of Revenue Ruling 89-81, whenever a fund has realized a long-term capital gain with respect to a given tax year, the fund must designate the required proportionate share of such capital gain to be included in common and preferred stock dividends. Applicants state that although rule 19b-1 allows a fund some flexibility with respect to the frequency of capital gains distributions, a fund might use all of the exceptions available under the rule for a tax year and still need to distribute additional capital gains allocated to the preferred stock to comply with Revenue Ruling 89-81.

³ Returns of capital as used in the application means return of capital for financial accounting purposes and not for tax accounting purposes.

10. Applicants assert that the potential abuses addressed by section 19(b) and rule 19b-1 do not arise with respect to preferred stock issued by a closed-end fund. Applicants assert that such distributions are fixed or determined in periodic auctions by reference to short-term interest rates rather than by reference to performance of the issuer and Revenue Ruling 89-81 determines the proportion of such distributions that are comprised of the long-term capital gains.

11. Applicants also submit that the "selling the dividend" concern is not applicable to preferred stock, which entitles a holder to no more than a periodic dividend at a fixed rate or the rate determined by the market, and, like a debt security, is priced based upon its liquidation value, dividend rate, credit quality, and frequency of payment. Applicants state that investors buy preferred shares for the purpose of receiving payments at the frequency bargained for, and do not expect the liquidation value of their shares to change.

12. Applicants request an order under section 6(c) granting an exemption from section 19(b) and rule 19b-1 to permit each Fund to make periodic capital gains dividends (as defined in section 852(b)(3)(C) of the Code) as often as monthly in any one taxable year in respect of its common shares and as often as specified by or determined in accordance with the terms thereof in respect of its preferred shares.

Applicants' Conditions

Applicants agree that any order granting the requested relief will be subject to the following conditions:

1. Compliance Review and Reporting

The Fund's chief compliance officer will: (a) Report to the Fund's Board, no less frequently than once every three months or at the next regularly scheduled quarterly Board meeting, whether (i) the Fund and its Investment Adviser have complied with the conditions to the order, and (ii) a Material Compliance Matter, as defined in rule 38a-1(e)(2) under the Act, has occurred with respect to compliance with such conditions; and (b) review the adequacy of the policies and procedures adopted by the Board no less frequently than annually.

2. Disclosures to Fund Shareholders

(a) Each 19(a) Notice disseminated to the holders of the Fund's common shares, in addition to the information required by section 19(a) and rule 19a-1:

(i) Will provide, in a tabular or graphical format:

(1) The amount of the distribution, on a per share basis, together with the amounts of such distribution amount, on a per share basis and as a percentage of such distribution amount, from estimated: (A) Net investment income; (B) net realized short-term capital gains; (C) net realized long-term capital gains; and (D) return of capital or other capital source;

(2) The fiscal year-to-date cumulative amount of distributions, on a per share basis, together with the amounts of such cumulative amount, on a per share basis and as a percentage of such cumulative amount of distributions, from estimated: (A) Net investment income; (B) net realized short-term capital gains; (C) net realized long-term capital gains; and (D) return of capital or other capital source;

(3) The average annual total return in relation to the change in NAV for the 5-year period (or, if the Fund's history of operations is less than five years, the time period commencing immediately following the Fund's first public offering) ending on the last day of the month ended immediately prior to the most recent distribution record date compared to the current fiscal period's annualized distribution rate expressed as a percentage of NAV as of the last day of the month prior to the most recent distribution record date; and

(4) The cumulative total return in relation to the change in NAV from the last completed fiscal year to the last day of the month prior to the most recent distribution record date compared to the fiscal year-to-date cumulative distribution rate expressed as a percentage of NAV as of the last day of the month prior to the most recent distribution record date.

Such disclosure shall be made in a type size at least as large and as prominent as the estimate of the sources of the current distribution; and

(ii) Will include the following disclosure:

(1) "You should not draw any conclusions about the Fund's investment performance from the amount of this distribution or from the terms of the Fund's Plan";

(2) "The Fund estimates that it has distributed more than its income and net realized capital gains; therefore, a portion of your distribution may be a return of capital. A return of capital may occur, for example, when some or all of the money that you invested in the Fund is paid back to you. A return of capital distribution does not necessarily reflect the Fund's investment performance and should not be

confused with 'yield' or 'income'";⁴ and

(3) "The amounts and sources of distributions reported in this 19(a) Notice are only estimates and are not being provided for tax reporting purposes. The actual amounts and sources of the amounts for tax reporting purposes will depend upon the Fund's investment experience during the remainder of its fiscal year and may be subject to changes based on tax regulations. The Fund will send you a Form 1099-DIV for the calendar year that will tell you how to report these distributions for Federal income tax purposes."

Such disclosure shall be made in a type size at least as large as and as prominent as any other information in the 19(a) Notice and placed on the same page in close proximity to the amount and the sources of the distribution;

(b) On the inside front cover of each report to shareholders under rule 30e-1 under the Act, the Fund will:

(i) Describe the terms of the Plan (including the fixed amount or fixed percentage of the distributions and the frequency of the distributions);

(ii) Include the disclosure required by condition 2(a)(ii)(1) above;

(iii) State, if applicable, that the Plan provides that the Board may amend or terminate the Plan at any time without prior notice to Fund shareholders; and

(iv) Describe any reasonably foreseeable circumstances that might cause the Fund to terminate the Plan and any reasonably foreseeable consequences of such termination; and

(c) Each report provided to shareholders under rule 30e-1 under the Act and each prospectus filed with the Commission on Form N-2 under the Act, will provide the Fund's total return in relation to changes in NAV in the financial highlights table and in any discussion about the Fund's total return.

3. Disclosure to Shareholders, Prospective Shareholders and Third Parties

(a) The Fund will include the information contained in the relevant 19(a) Notice, including the disclosure required by condition 2(a)(ii) above, in any written communication (other than a communication on Form 1099) about the Plan or distributions under the Plan by the Fund, or agents that the Fund has authorized to make such communication on the Fund's behalf, to any Fund common shareholder,

⁴ The disclosure in this condition 2(a)(ii)(2) will be included only if the current distribution or the fiscal year-to-date cumulative distributions are estimated to include a return of capital.

prospective common shareholder or third-party information provider;

(b) The Fund will issue, contemporaneously with the issuance of any 19(a) Notice, a press release containing the information in the 19(a) Notice and will file with the Commission the information contained in such 19(a) Notice, including the disclosure required by condition 2(a)(ii) above, as an exhibit to its next filed Form N-CSR; and

(c) The Fund will post prominently a statement on its (or the Investment Adviser's) Web site containing the information in each 19(a) Notice, including the disclosure required by condition 2(a)(ii) above, and will maintain such information on such Web site for at least 24 months.

4. Delivery of 19(a) Notices to Beneficial Owners

If a broker, dealer, bank or other person ("financial intermediary") holds common stock issued by the Fund in nominee name, or otherwise, on behalf of a beneficial owner, the Fund: (a) Will request that the financial intermediary, or its agent, forward the 19(a) Notice to all beneficial owners of the Fund's shares held through such financial intermediary; (b) will provide, in a timely manner, to the financial intermediary, or its agent, enough copies of the 19(a) Notice assembled in the form and at the place that the financial intermediary, or its agent, reasonably requests to facilitate the financial intermediary's sending of the 19(a) Notice to each beneficial owner of the Fund's shares; and (c) upon the request of any financial intermediary, or its agent, that receives copies of the 19(a) Notice, will pay the financial intermediary, or its agent, the reasonable expenses of sending the 19(a) Notice to such beneficial owners.

5. Additional Board Determinations for Funds Whose Shares Trade at a Premium

If:

(a) The Fund's common shares have traded on the stock exchange that they primarily trade on at the time in question at an average premium to NAV equal to or greater than 10%, as determined on the basis of the average of the discount or premium to NAV of the Fund's common shares as of the close of each trading day over a 12-week rolling period (each such 12-week rolling period ending on the last trading day of each week); and

(b) The Fund's annualized distribution rate for such 12-week rolling period, expressed as a percentage of NAV as of the ending date of such 12-

week rolling period, is greater than the Fund's average annual total return in relation to the change in NAV over the 2-year period ending on the last day of such 12-week rolling period;

then:

(i) At the earlier of the next regularly scheduled meeting or within four months of the last day of such 12-week rolling period, the Board including a majority of the Independent Trustees:

(1) Will request and evaluate, and the Investment Adviser will furnish, such information as may be reasonably necessary to make an informed determination of whether the Plan should be continued or continued after amendment;

(2) Will determine whether continuation, or continuation after amendment, of the Plan is consistent with the Fund's investment objective(s) and policies and is in the best interests of the Fund and its shareholders, after considering the information in condition 5(b)(i)(1) above; including, without limitation:

(A) Whether the Plan is accomplishing its purpose(s);

(B) The reasonably foreseeable material effects of the Plan on the Fund's long-term total return in relation to the market price and NAV of the Fund's common shares; and

(C) The Fund's current distribution rate, as described in condition 5(b) above, compared with the Fund's average annual taxable income or total return over the 2-year period, as described in condition 5(b), or such longer period as the Board deems appropriate; and

(3) Based upon that determination, will approve or disapprove the continuation, or continuation after amendment, of the Plan; and

(ii) The Board will record the information considered by it, including its consideration of the factors listed in condition 5(b)(i)(2) above, and the basis for its approval or disapproval of the continuation, or continuation after amendment, of the Plan in its meeting minutes, which must be made and preserved for a period of not less than six years from the date of such meeting, the first two years in an easily accessible place.

6. Public Offerings

The Fund will not make a public offering of the Fund's common shares other than:

(a) A rights offering below NAV to holders of the Fund's common shares;

(b) An offering in connection with a dividend reinvestment plan, merger, consolidation, acquisition, spin-off or reorganization of the Fund; or

(c) An offering other than an offering described in conditions 6(a) and 6(b) above, provided that, with respect to such other offering:

(i) The Fund's annualized distribution rate for the six months ending on the last day of the month ended immediately prior to the most recent distribution record date,⁵ expressed as a percentage of NAV per share as of such date, is no more than 1 percentage point greater than the Fund's average annual total return for the 5-year period ending on such date;⁶ and

(ii) The transmittal letter accompanying any registration statement filed with the Commission in connection with such offering discloses that the Fund has received an order under section 19(b) to permit it to make periodic distributions of long-term capital gains with respect to its common stock as frequently as twelve times each year, and as frequently as distributions are specified by or determined in accordance with the terms of any outstanding preferred stock as such Fund may issue.

7. Amendments to Rule 19b-1

The requested order will expire on the effective date of any amendment to rule 19b-1 that provides relief permitting certain closed-end investment companies to make periodic distributions of long-term capital gains with respect to their outstanding common stock as frequently as twelve times each year.

For the Commission, by the Division of Investment Management, under delegated authority.

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E9-25422 Filed 10-21-09; 8:45 am]

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⁵ If the Fund has been in operation for less than six months, the measured period will begin immediately following the Fund's first public offering.

⁶ If the Fund has been in operation for less than five years, the measured period will begin immediately following the Fund's first public offering.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-60826; File No. SR-BX-2009-062]

Self-Regulatory Organizations; NASDAQ OMX BX; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Rule 7015 Governing Access Services To Add an Additional Service and Related Fee, and To Make a Technical Change

October 14, 2009.

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 October 5, 2009, NASDAQ OMX BX, Inc. ("BX") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by BX. 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

BX proposes to amend Rule 7015 to make a new service, TradeInfo BX, available to members and charge a related fee. The text of the proposed rule change is below. Proposed new language is italicized and proposed deletions are in brackets.

7015. Access Services

The following charges are assessed by the Exchange for ports to establish connectivity to the NASDAQ OMX BX Equities Market, as well as ports to receive data from the NASDAQ OMX BX Equities Market:

- \$400 per month for each port pair, other than Multicast ITCH® data feed pairs, for which the fee is \$1000 per month. [Additional OUCH port pairs beyond 15 are at no cost for the months of May, June and July 2009. For August 2009, OUCH port pairs beyond 15 will be assessed a pro rata charge on the basis of the number of trading days during the month during which the anti-internalization functionality introduced by Equity Rule 4757(a)(3) is available to market participants.]

- Internet Ports: An additional \$200 per month for each Internet port that requires additional bandwidth.

- TradeInfo BX is available to Members for a fee of \$95 per user per month.

* * * *

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, BX 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. BX 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

BX proposes to amend Rule 7015 to initiate fees of \$95 per month per user for its Web-based TradeInfo BX product. Through a secure Web connection, TradeInfo BX allows subscribing members to scan for their orders submitted to BX. Members can scan for all orders in a particular security or all orders of a particular type, regardless of their status (open, canceled, executed, etc.). Members are also able to cancel open orders at the order, port or MPID level. For example, after scanning for open orders, the member is then able to select an open order and cancel the order. TradeInfo BX also allows members to scan other order statuses, such as executed, cancelled, broken, rejected and suspended orders. TradeInfo BX enables members to generate reports of execution, order or cancel information, which can be exported into a spreadsheet for review. Under the proposed rule, TradeInfo BX will be available solely to BX members.

The Nasdaq Stock Market ("Nasdaq") TradeInfo product is currently offered to Nasdaq members and BX is proposing to offer the same functionality to BX members with respect to BX equity orders as is provided to Nasdaq members with respect to their Nasdaq equity orders. BX notes that in December 2006, Nasdaq filed with the Commission a rule change to charge subscribing Nasdaq members \$95 per month, per user for the Nasdaq-based TradeInfo product.³ Because the TradeInfo BX product provides the same functionality with respect to BX members' equity orders on BX as is provided by the Nasdaq TradeInfo product with respect to Nasdaq equity

orders, BX is proposing to offer TradeInfo BX for the same fee of \$95 per month, per user as is currently charged by Nasdaq.

BX is also proposing to eliminate language from Rule 7015 that discusses temporary pricing for additional OUCH port pairs beyond 15, which has since expired. BX suspended fees for OUCH port pairs for the months of May, June and July 2009 so that BX could implement an anti-internalization function, the absence of which was causing members to purchase additional OUCH ports that they would otherwise not need solely to avoid unwanted execution against their customer orders.⁴ With the anticipated August 2009 implementation of the anti-internalization function, BX adopted a pro-rated fee for the month of August 2009 based on the number of trading days the anti-internalization function was available in that month.⁵ The anti-internalization function was implemented on August 3, 2009. Accordingly, BX is eliminating reference in Rule 7015 to the temporary pricing.

2. Statutory Basis

BX believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,⁶ in general, and with Section 6(b)(4) of the Act,⁷ in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system which BX operates or controls. The proposed fee change applies uniformly to all BX members and is equal to the fee charged to Nasdaq members for the same functionality provided with respect to Nasdaq orders.

BX also believes that the proposed rule change is consistent with the provisions of Section 6(b)(5) of the Act⁸ in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to

and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The proposed rule change amends Rule 7015 to add TradeInfo BX, a new Web-based product available to BX members to assist them with their management of BX orders, a Nasdaq version of which is currently offered to Nasdaq members for their Nasdaq orders. In addition, BX is proposing to offer the new product to BX members for the same fee as is currently charged to Nasdaq members for the analogous Nasdaq product. Last, BX is proposing to eliminate rule text that had a limited timeframe during which it applied, which has since expired. The elimination of the expired rule text will serve to avoid potential confusion that may be caused by keeping such text in the rules.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments were neither solicited nor received.

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 Act⁹ and Rule 19b-4(f)(6) thereunder.¹⁰

A proposed rule change filed pursuant to Rule 19b-4(f)(6) under the Act¹¹ normally does not become operative for 30 days after the date of its filing. However, Rule 19b-4(f)(6)¹² permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the

³ Securities Exchange Act Release No. 55135 (January 19, 2007), 72 FR 3893 (January 26, 2007) (SR-NASDAQ-2006-062).

⁴ Securities Exchange Act Release No. 59894 (May 8, 2009), 74 FR 23000 (May 15, 2009) (SR-BX-2009-023); see also Securities Exchange Act Release No. 60257 (July 7, 2009), 74 FR 34060 (July 14, 2009) (SR-BX-2009-036).

⁵ Securities Exchange Act Release No. 60503 (August 14, 2009), 74 FR 42346 (August 21, 2009) (SR-BX-2009-046).

⁶ 15 U.S.C. 78f.

⁷ 15 U.S.C. 78f(b)(4).

⁸ 15 U.S.C. 78f(b)(5).

⁹ 15 U.S.C. 78s(b)(3)(A).

¹⁰ 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file 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. BX has satisfied this requirement.

¹¹ 17 CFR 240.19b-4(f)(6).

¹² 17 CFR 240.19b-4(f)(6).

public interest. BX requests that the Commission waive the 30-day operative delay so that this proposed rule change to implement TradeInfo BX will immediately assist BX members in the management of their orders. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because it will allow BX members the capability to scan their orders, cancel open orders (*e.g.*, should the member experience technical difficulties with its systems or connections), and reconcile its record of orders against data provide in the TradeInfo BX reports.¹³ Additionally, this product will allow subscribing members to immediately take advantage of the different types of TradeInfo BX open order cancellation capabilities: either canceling a single open order, canceling all open orders associated with a particular connection, or canceling all open orders associate with a particular MPID. Application of the new rule should help foster consistency among those exchanges that adopt rules substantially similar to those previously approved by the Commission.¹⁴ For these reasons, the Commission designates that the proposed rule change become immediately operative.

At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an e-mail to rule-comments@sec.gov. Please include File Number SR-BX-2009-062 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary,

¹³ For purposes only of waiving the 30-day operative delay, the Commission has considered the proposal's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

¹⁴ See *supra* note 3 and accompanying text.

Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549-1090.

All submissions should refer to File Number SR-BX-2009-062. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of 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 publicly available. All submissions should refer to File Number SR-BX-2009-062 and should be submitted on or before November 12, 2009.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁵

Florence E. Harmon,
Deputy Secretary.

[FR Doc. E9-25339 Filed 10-21-09; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-60832; File No. SR-BX-2009-066]

Self-Regulatory Organizations; NASDAQ OMX BX, Inc.; Notice of Filing and Order Granting Accelerated Approval of Proposed Rule Change Relating to Chapter XII of the BOX Rules

October 16, 2009.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934

¹⁵ 17 CFR 200.30-3(a)(12).

(“Act”)¹ and Rule 19b-4 thereunder,² notice is hereby given that on October 14, 2009, NASDAQ OMX BX, Inc. (the “Exchange”) filed with the Securities and Exchange Commission (“Commission”) the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons, and is approving the proposal on an accelerated basis.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Chapter XII of the Boston Options Exchange (“BOX”) Rules by adding a new Section 5. The text of the proposed rule change is available at the Commission's Public Reference Room, the principal office of the Exchange, and on its Web site at <http://nasdaqomxbx.cchwallstreet.com/NASDAQOMXBX/Filings>.

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 in the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange amended Chapter XII of the BOX Rules to reflect the Exchange's filing to become a participant in the Options Order Protection and Locked/Crossed Market Plan (“Decentralized Plan”).³ The Decentralized Plan applies many of the Regulation NMS⁴ price-

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See Securities Exchange Act Release No. 60405 (July 30, 2009), 74 FR 39362 (August 6, 2009) (File No. 4-546) (Order Approving the National Market System Plan Relating to Options Order Protection and Locked/Crossed Market Plan). Terms not otherwise defined herein shall have the meaning proscribed in the BOX Rules.

⁴ See Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496 (June 29, 2005).

protection provisions to the options markets. Similar to Regulation NMS, the Decentralized Plan requires Plan Participants to, among other things, adopt rules “reasonably designed to prevent Trade-Throughs⁵ in Eligible Options Classes⁶”, while providing exceptions for certain transactions that track those provided under Regulation NMS, correspond with unique aspects of the options market, or both.⁷

The Commission previously approved certain Exchange rules and definitions necessary to implement the Decentralized Plan.⁸ The purpose of this filing is to amend Chapter XII of the BOX Rules to provide for the use by BOX of certain non-affiliated third party routing broker/dealers (“Routing Broker(s)”) to route options orders to one or more Away Exchange(s) when such Away Exchange(s) display the Best Bid or Best Offer in accordance with the Decentralized Plan. In particular, the Exchange proposes to add to Chapter XII of the BOX Rules, a new rule that would

⁵ A “Trade-Through” is defined as a transaction in an options series, either as principal or agent, at a price that is lower than a Protected Bid or higher than a Protected Offer. See Section 2(21) of the Decentralized Plan; see also Chapter XII, Section 1(g) of the BOX Rules. A “Protected Bid” or a “Protected Offer” means a Bid or Offer in an option series, respectively, that is disseminated pursuant to the OPRA Plan and is the Best Bid or Best Offer, respectively, displayed by an Eligible Exchange. See Section 2(17) of the Decentralized Plan; see also Chapter XII, Section 1(n) of the BOX Rules. A “Best Bid” or “Best Offer” means the highest priced Bid or the lowest priced Offer. See Section 2(1) of the Decentralized Plan; see also Chapter XII, Section 1(a) of the BOX Rules. A “Bid” or “Offer” means the bid price or the offer price communicated by a member of an Eligible Exchange to any Broker/Dealer, or to any customer, at which it is willing to buy or sell, as either principal or agent, but would not include indications of interest. See Section 2(2) of the Decentralized Plan; see also Chapter XII, Section 1(b) of the BOX Rules.

⁶ An “Eligible Options Class” is defined as all options series overlying a security (as that term is defined in Section 3(a)(10) of the Exchange Act) or group of securities, including both put options and call options, which class is traded on BOX and at least one other Eligible Exchange. See Section 2(7) of the Decentralized Plan; see also Chapter XII, Temporary Section 4(g)(2) of the BOX Rules. An “Eligible Exchange” means a national securities exchange registered with the Commission in accordance with Section 6(a) of the Securities Exchange Act of 1934 (“Act”) that is a Participant Exchange in OCC (as that term is defined in Section VII of the OCC by-laws), is a party to the OPRA Plan (as that term is defined in Section I of the OPRA Plan), and if the national securities exchange is not a party to the Plan, is a participant in another plan approved by the Commission providing for comparable Trade-Through and Locked and Crossed Market protection. See Section 2(6) of the Decentralized Plan; see also Chapter XII, Section 1(f).

⁷ See Section 5(b) of the Decentralized Plan.

⁸ See Securities Exchange Act Release No. 60530 (August 18, 2009), 74 FR 43200 (August 26, 2009) (SR-BX-2009-028).

govern the outbound order routing process (“Order Routing Rule”).⁹

The use of the Routing Broker to route orders to one or more Away Exchange(s) will be optional and available only to BOX Options Participants. In the event an Options Participant does not want to use the Routing Broker it must simply designate the order as do not route.¹⁰ Only orders that are specifically designated by Options Participants as eligible for routing will be routed to an Away Exchange (“Eligible Orders”). However, Market-on-Opening Orders, any Improvement Auction orders or any order identified with the condition “Fill and Kill” shall not be eligible for routing. BOX would only route an Eligible Order in order to avoid a Trade-Through or a locked or crossed market, pursuant to the requirements of Chapter XII, Sections 2 and 3 of the BOX Rules and consistent with the Decentralized Plan, when the order has not been executed in its entirety on BOX.¹¹ All Eligible Orders entered on BOX that are routed via the Routing Broker that result in an execution shall be binding on the Options Participant that entered such Eligible Order.

The full or remaining quantity of an Eligible Order will be routed to one or more Away Exchange(s) as Immediate or Cancel (“IOC”) limit order(s) priced at the current NBBO. Multiple IOC limit order(s) may be routed to Away Exchanges with the best Protected Bid or Protected Offer until the Eligible Order quantity is fully executed or the limit price is reached. If the Eligible Order is not executed in its entirety at the Away Exchange(s) or its limit price is reached, then it will be returned to BOX and the remainder of the Eligible Order will be treated as a new order. While an Eligible Order remains outside BOX, it would have no time standing relative to other orders received from Options Participants at the same price that could be executed against interest on the BOX Book. Requests from Options Participants to cancel their Eligible Order while routed to one or more Away Exchange(s) would be processed subject to the applicable trading rules of the Away Exchange(s).

As stated above, the Exchange proposes that BOX would route Eligible Orders to Away Exchanges under certain circumstances (“Routing Services”). BOX would provide its

⁹ See proposed Chapter XII, Section 5 of the BOX Rules.

¹⁰ Options Participants must indicate for each order whether the order is eligible for routing or not.

¹¹ At this time BOX will not be sending ISOs to Away Markets, as defined in Chapter V, Section 14(c)(vi) of the BOX Rules.

Routing Services pursuant to the terms of an agreement between BOX and each Routing Broker that provides Routing Services (“BOX Routing Agreement”).

The Exchange proposes that BOX provide its Routing Services in compliance with its own rules and with the provisions of the Act and the rules thereunder, including, but not limited to, the requirements in Sections 6(b)(4) and (5) of the Act¹² that the rules of a national securities exchange provide for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities, and not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

As a provider of Routing Services, the Exchange proposes that BOX would enter into a Routing Agreement for the necessary routing technology to be used in connection with its own systems and accordingly would control the logic that determines when, how, and where orders are routed to Away Exchanges. The Routing Broker cannot change the routing logic.

The Exchange also proposes that BOX establish and maintain procedures and internal controls reasonably designed to adequately restrict the flow of confidential and proprietary information between BOX and the Routing Broker, and any other entity, including any affiliate of the Routing Broker, and, to the extent the Routing Broker reasonably receives confidential and proprietary information, that adequately restrict the use of such information by the Routing Broker to legitimate business purposes necessary for routing orders at the direction of BOX; and, if the Routing Broker or any of its affiliates engages in any other business activities other than providing routing services to BOX, between the segment of the Routing Broker or affiliate that provides the other business activities and the segment of the Routing Broker that provides the routing services.¹³ The Routing Agreement would include terms and conditions that enable BOX to comply with these proposed requirements.

The Exchange requests that this proposal be approved on a pilot basis for three (3) months starting from the date of the approval of this filing.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the requirements of Section 6(b) of the

¹² 15 U.S.C. 78f(b)(4) and (5).

¹³ BOX may not use a Routing Broker for which the Exchange or any affiliate of the Exchange is the designated examining authority.

Act,¹⁴ in general, and Section 6(b)(5) of the Act,¹⁵ in particular, in that it will promote just and equitable principles of trade; facilitate transactions in securities; remove impediments to and perfect the mechanism of a free and open market and a national market system; and, in general, protect investors and the public interest. The Exchange believes that the proposed rule change also is designed to support the principles of Section 11A(a)(1)¹⁶ in that it seeks to assure economically efficient execution of securities transactions. In particular, the proposed rule change will allow BOX to establish and implement mechanisms to remain fully compliant with the Decentralized Plan, BOX Rules, and its best execution obligations.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has neither solicited nor received comments on the proposed rule change.

III. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an e-mail to rule-comments@sec.gov. Please include File Number SR-BX-2009-066 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549-1090.

All submissions should refer to File Number SR-BX-2009-066. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your

comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-BX-2009-066 and should be submitted on or before November 12, 2009.

IV. Commission's Findings and Order Granting Accelerated Approval of a Proposed Rule Change

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.¹⁷ In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,¹⁸ which requires, among other things, that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices; to promote just and equitable principles of trade; to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities; to remove impediments to and perfect the mechanism of a free and open market and a national market system; and, in general, to protect investors and the public interest; and are not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

As described above, BOX Options Participants may designate orders to be

routed to another market center when trading interest is not available on BOX. Orders designated for routing will be routed to avoid a Trade-Through or a locked or crossed market, when an order has not been executed in its entirety on BOX. Orders routed to other markets do not retain time priority with respect to orders on BOX. If a routed order is returned to BOX in whole or in part, that order (or remainder) will be treated as a new order, with a new time stamp. All orders entered on BOX that are routed via the Routing Broker that result in an execution shall be binding on the BOX Options Participant that entered such order.

Use of the Exchange's Routing Services will be optional,¹⁹ and the Exchange will be responsible for routing decisions and will retain control of the routing logic.²⁰ Neither the Exchange, nor any affiliate of the Exchange, may be the designated examining authority for a Routing Broker.²¹ The Commission also notes that the rule contemplates procedures and internal controls designed to protect confidential and proprietary information, which should help ensure that a Routing Broker does not misuse routing information obtained from the Exchange. In addition, the Exchange will provide its Routing Services in compliance with its own rules and with the provisions of the Act and the rules thereunder, including, but not limited to, the requirements in Sections 6(b)(4) and (5) of the Act²² that the rules of a national securities exchange provide for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities, and not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.²³ In light of these protections, the Commission believes that BOX's rules and procedures regarding the Routing Services are consistent with the Act.

The Exchange has asked the Commission to accelerate approval of the proposed rule change. The Exchange notes that its proposal is consistent with prior Commission action,²⁴ and that accelerated approval will allow BOX to establish and implement mechanisms to remain fully compliant with the

¹⁹ See *supra* note 10.

²⁰ See *supra* note 13.

²¹ See proposed BOX Rule Chapter XII, Section 5, Supplementary Material .01(d).

²² 15 U.S.C. 78f(b)(4) and (5).

²³ See proposed BOX Rule Chapter XII, Section 5, Supplementary Material .01(a).

²⁴ See SR-BX-2009-066, Item 7; see also Securities Exchange Act Release No. 60551 (August 20, 2009), 73 FR 43196 (August 26, 2009) (SR-CBOE-2009-040).

¹⁴ 15 U.S.C. 78(f)(b).

¹⁵ 15 U.S.C. 78(f)(b)(5).

¹⁶ 15 U.S.C. 78k-1(a)(1).

¹⁷ In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

¹⁸ 15 U.S.C. 78f(b)(5).

Decentralized Plan and BOX Rules. The Exchange also states that accelerated approval will allow BOX to be fully compliant with the Decentralized Plan and no longer rely on a Commission-granted exemption²⁵ from Rule 608(c) of Regulation NMS, which requires BOX to comply with, and enforce compliance by its members with, certain provisions of the Decentralized Plan.²⁶ The exemption is currently set to expire on October 31, 2009.²⁷ The Commission finds good cause for approving the proposed rule change before the thirtieth day after the date of publication of notice of filing thereof in the **Federal Register**. The Commission notes that the Exchange's proposal is consistent with rules approved for other national securities exchanges.²⁸ Also, approval on an accelerated basis will allow BOX an opportunity to comply with the terms of the Decentralized Plan prior to the expiration of its exemption, while the proposed pilot period will allow interested parties an opportunity to comment on the proposal before permanent approval. Accordingly, the Commission finds good cause, consistent with Section 19(b)(2) of the Act,²⁹ to approve the proposed rule change on an accelerated basis for a pilot period expiring January 15, 2010.

V. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act, that the proposed rule change (SR-BX-2009-066) is hereby approved on an accelerated basis for a pilot period to expire on January 15, 2010.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.³⁰

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E9-25338 Filed 10-21-09; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-60824; File No. SR-FINRA-2009-066]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing of Proposed Rule Change To Adopt FINRA Rule 2251 (Forwarding of Proxy and Other Issuer-Related Materials) in the Consolidated FINRA Rulebook

October 14, 2009.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act" or "SEA")¹ and Rule 19b-4 thereunder,² notice is hereby given that on October 2, 2009, Financial Industry Regulatory Authority, Inc. ("FINRA") (f/k/a National Association of Securities Dealers, Inc. ("NASD")) 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. 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 adopt without material change NASD Rule 2260 (Forwarding of Proxy and Other Materials) and NASD IM-2260 (Approved Rates of Reimbursement) in the consolidated FINRA rulebook. The proposed rule change would combine NASD Rule 2260 and NASD IM-2260 into a single rule that would be renumbered as FINRA Rule 2251 in the consolidated FINRA rulebook.

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.

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

As part of the process of developing a new consolidated rulebook ("Consolidated FINRA Rulebook"),³ FINRA is proposing to adopt without material change NASD Rule 2260 (Forwarding of Proxy and Other Materials) and NASD Interpretive Material ("IM") 2260 (Approved Rates of Reimbursement) in the Consolidated FINRA Rulebook. The proposed rule change would combine NASD Rule 2260 and NASD IM-2260 into a single rule that would be renumbered as FINRA Rule 2251 in the Consolidated FINRA Rulebook.

(A) Background

NASD Rule 2260 sets forth certain requirements with respect to the transmission of proxy materials and other communications to beneficial owners of securities and the limited circumstances in which members are permitted to vote proxies without instructions from those beneficial owners. NASD IM-2260 regulates the reimbursement that members are entitled to receive in connection with forwarding proxy materials and other communications.

(1) NASD Rule 2260

NASD Rule 2260(a) sets forth the general obligation of members to transmit proxy and related materials. The rule provides that members must, in connection with an equity security, forward promptly⁴ or, in connection with a debt security, make reasonable efforts to forward promptly certain information to the beneficial owner,⁵ or

³ The current FINRA rulebook consists of: (1) FINRA Rules; (2) NASD Rules; and (3) rules incorporated from NYSE ("Incorporated NYSE Rules") (together, the NASD Rules and Incorporated NYSE Rules are referred to as the "Transitional Rulebook"). While the NASD Rules generally apply to all FINRA members, the Incorporated NYSE Rules apply only to those members of FINRA that are also members of the NYSE ("Dual Members"). The FINRA Rules apply to all FINRA members, unless such rules have a more limited application by their terms. For more information about the rulebook consolidation process, see *Information Notice*, March 12, 2008 (Rulebook Consolidation Process).

⁴ SEA Rule 14b-1(b)(2) requires that broker-dealers must forward proxy and other specified materials no later than five business days after receipt.

⁵ Under paragraph (e) of the rule, a member's duty under Rule 2260(a) applies provided the member: is furnished with sufficient copies of the material (e.g., annual reports, information statements or other material sent to security holders) by the issuer, stockholder or trustee; is requested by the issuer, stockholder or trustee to forward the

²⁵ See letter from Elizabeth K. King, Associate Director, Division of Trading and Markets, Commission, to Maura A. Looney, Associate Vice President, NASDAQ OMX BX, Inc., dated August 28, 2009 (granting the Exchange's request under Rule 608(e) of Regulation NMS for a Temporary Exemption from Certain Provisions of the Options Order Protection and Locked/Crossed Market Plan) ("Exemption Letter").

²⁶ See SR-BX-2009-066, Item 7.

²⁷ See Exemption Letter, *supra* note 25.

²⁸ See, e.g., *supra* note 24.

²⁹ 15 U.S.C. 78s(b)(2).

³⁰ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

the beneficial owner's designated investment adviser,⁶ if the member carries the account in which the security is held for the beneficial owner and the security is registered in a name other than the name of the beneficial owner (*i.e.*, the member holds the security in "street name").

With respect to proxy materials, NASD Rule 2260(c)(1) generally requires that whenever an issuer or stockholder of the issuer soliciting proxies timely furnishes to a member sufficient copies of all soliciting material, as well as satisfactory assurance that it will reimburse the member for all out-of-pocket expenses, the member must transmit promptly to each beneficial owner of stock of the issuer that is in its possession or control all the material furnished. The rule addresses what must be included with the proxy materials and incorporates by reference certain recordkeeping requirements under SEA Rule 17a-4.

NASD Rule 2260(b) generally prohibits a member from giving a proxy to vote stock that is registered in its name unless the member is the beneficial owner of the stock (*i.e.*, the rule generally bars members from giving proxies to vote without instructions from the beneficial owner). However, the rule sets forth certain exceptions. Rule 2260(c)(2) provides that a member may give a proxy to vote any stock pursuant to the rules of any national securities exchange to which the member is also responsible⁷ provided that the records of the member clearly indicate the procedure it is following.⁸ (Similar to Rule 2260(e)(2), Rule 2260(c)(3) provides that the rule's proxy transmission requirements do not apply

material to security holders; and receives satisfactory assurance that it will be reimbursed by the issuer, stockholder or trustee for all out-of-pocket expenses, including reasonable clerical expenses. Rule 2260(e)(2) provides that paragraph (e) does not apply to beneficial owners residing outside the U.S. The rule states that members may voluntarily comply with the rule's provisions with respect to such persons if they wish.

⁶ The term "designated investment adviser" is defined in paragraph (f) of the rule.

⁷ The phrase "national securities exchange to which the member is also responsible" refers to a national securities exchange to which the member belongs. See Securities Exchange Act Release No. 35681 (May 5, 1995), 60 FR 25749 (May 12, 1995) (Order Approving Proposed Rule Change; File No. SR-NASD-95-06); see also *Notice to Members* 95-45 (June 1995).

⁸ FINRA notes that, with respect to compliance by Dual Members, the SEC recently approved amendments to non-Incorporated NYSE Rules (*i.e.*, NYSE Rules that were not incorporated by FINRA into its rulebook) that eliminate discretionary voting by brokers under certain circumstances. See Securities Exchange Act Release No. 60215 (July 1, 2009), 74 FR 33293 (July 10, 2009) (Order Approving Proposed Rule Change; File No. SR-NYSE-2006-92).

to beneficial owners residing outside the U.S. The rule states that members may voluntarily comply with the rule's provisions with respect to such persons if they wish.) Rule 2260(d)(1) provides that a member may give a proxy to vote any stock registered in its name if the member holds the stock as executor, administrator, guardian, trustee, or in a similar representative or fiduciary capacity with authority to vote. Rule 2260(d)(3) generally permits any member designated by a named Employee Retirement Income Security Act of 1974 (as amended) ("ERISA") Plan fiduciary as the investment manager of stock held as assets of the ERISA Plan to vote the proxies in accordance with the ERISA Plan fiduciary responsibilities, subject to certain conditions. Further, the rule permits designated investment advisers to vote the proxies.

(2) NASD IM-2260

IM-2260 addresses the rates of reimbursement that are considered reasonable for purposes of Rule 2260 in connection with the rule's forwarding obligations. The IM has been amended a number of times, most recently in 2003 for the purpose of aligning the IM's requirements with the fee structures adopted by the NYSE and Amex.⁹ Broadly, the IM addresses three areas:

- IM-2260(a) provides that members, in addition to charges specified in IM-2260(a)(1) through (5),¹⁰ also are entitled to receive reimbursement for certain postage and stationery costs, as well as certain communication expenses incurred in receiving voting returns either telephonically or electronically;
- IM-2260(b) reminds members that NASD Rule 2430 requires that any charges must be reasonable.¹¹ The IM provides that members may request reimbursement of expenses at less than the approved rates; however, no member may seek reimbursement at rates higher than the approved rates or

⁹ See Securities Exchange Act Release No. 47392 (February 21, 2003), 68 FR 9730 (February 28, 2003) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change; File No. SR-NASD-2003-019).

¹⁰ IM-2260(a)(1) through (5) specify the charges for: (1) initial proxy and/or annual report mailings; (2) proxy follow-up mailings; (3) providing beneficial ownership information; (4) interim report, post meeting report and other material mailings; and (5) incentive fees (fees with respect to each account where the member has eliminated the need to send materials in paper format through the mails).

¹¹ NASD Rule 2430 provides, among other things, that charges for services performed must be "reasonable" and "not unfairly discriminatory between customers." (FINRA will address Rule 2430 at a later phase in the rulebook consolidation process.)

for items or services not specifically listed in the IM without the prior notification to and consent of the person soliciting proxies or the company;

- IM-2260(c) generally permits members to avoid transmitting multiple copies of materials to beneficial owners having more than one account or sharing the same address, provided members comply with applicable SEC rules.

(B) Proposal

FINRA believes that NASD Rule 2260 and IM-2260 provide effective protection to investors. Accordingly, FINRA proposes to combine the two rules, without material change, into a single rule that would be renumbered as FINRA Rule 2251 in the Consolidated FINRA Rulebook.¹² The proposed rule change would make minor clarifying changes and other changes primarily to reflect the new formatting and terminology conventions of the Consolidated FINRA Rulebook.¹³ In addition, because a number of requirements set forth by the rule also are addressed by the SEC's proxy rules, the proposed rule change would add language where appropriate to remind members that they are obligated to comply both with the FINRA rule and applicable SEC rules and/or guidance. With respect to the requirement set forth in NASD Rule 2260(a) that members forward those materials that are properly furnished to the member, the proposed rule change would clarify that firms are required to forward the materials subject to paragraphs (c) and (e) of the rule, as applicable. With respect to NASD Rule 2260(c)(2)'s provisions allowing a member to give a proxy to vote any stock pursuant to the rules of "any national securities exchange to which the member is also responsible," proposed FINRA Rule 2251 would read "any national securities exchange of which it is a member." FINRA believes the latter expression is clearer and reflects FINRA's longstanding interpretation of the rule language.¹⁴

FINRA will announce the implementation date of the proposed

¹² NASD IM-2260 would be redesignated as Supplementary Material within proposed FINRA Rule 2251.

¹³ For example, the language in NASD Rule 2260(a) stating that a member "has an inherent duty" to forward materials would be revised to state that a member "shall" forward such materials. Further, the proposed rule change would move the footnoted provisions defining the terms "ERISA" and "state" to the rule text, and the footnoted provision regarding verification of investment advisers would be redesignated as Supplementary Material.

¹⁴ See note 7 *supra*.

rule change in a *Regulatory Notice* to be published no later than 90 days following Commission approval.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,¹⁵ 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, as part of the Consolidated FINRA Rulebook, the proposed rule change will protect investors and the public interest by addressing the forwarding of proxy and other issuer-related materials.

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.

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.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) by order approve such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an e-mail to rule-comments@sec.gov. Please include File Number SR-FINRA-2009-066 on the subject line.

Paper Comments

- Send paper comments in triplicate to Florence E. Harmon, Deputy Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549-1090.

All submissions should refer to File Number SR-FINRA-2009-066. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of 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-2009-066 and should be submitted on or before November 12, 2009.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁶

Florence E. Harmon,
Deputy Secretary.

[FR Doc. E9-25427 Filed 10-21-09; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-60834; File No. SR-NYSEArca-2009-88]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending Its Schedule of Fees and Charges for Exchange Services

October 16, 2009.

Pursuant to Section 19(b)(1)¹ of the Securities Exchange Act of 1934 (the "Act")² and Rule 19b-4 thereunder,³ notice is hereby given that, on September 30, 2009, NYSE Arca, Inc. ("NYSE Arca" or the "Exchange") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. NYSE Arca filed the proposal pursuant to Section 19(b)(3)(A)⁴ of the Act and Rule 19b-4(f)(2)⁵ thereunder. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the section of its Schedule of Fees and Charges for Exchange Services (the "Schedule"). While changes to the Schedule pursuant to this proposal will be effective upon filing, the changes will become operative on October 1, 2009. A copy of this filing is available on the Exchange's Web site at <http://www.nyse.com>, at the Exchange's principal office and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below,

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.

⁴ 15 U.S.C. 78s(b)(3)(A).

⁵ 17 CFR 240.19b-4(f)(2).

¹⁵ 15 U.S.C. 78o-3(b)(6).

¹⁶ 17 CFR 200.30-3(a)(12).

of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to make changes to its Schedule that will take effect on October 1, 2009. A more detailed description of the proposed changes follows.

PO and PO+ Orders routed to Amex:

The Exchange proposes to add a new rate for PO and PO+ orders (collectively "PO Orders") routed to Amex in Tape B securities. The Exchange will pay a \$0.0030 per share credit for PO Orders routed to Amex that provide liquidity to the NYSE Amex Book. The Exchange will also charge a fee of \$0.0025 per share for PO Orders routed to Amex that remove liquidity from the NYSE Amex Book. These fees will mirror the inverted pricing available on Amex, also scheduled to become effective on October 1, 2009.

Auction Orders:

The Exchange also proposes to charge \$0.0007 for Market-On-Close ("MOC") and Limit-On-Close ("LOC") orders executed in the Closing Auction in all Tape A and Tape C securities. The proposed rate is applicable to all tiers and basic rate pricing. This brings the rate in line with the current rate charged for MOC/LOC orders executed in Tape C ETF and ETNs. The Exchange also proposes to charge \$0.0007 for PO Orders routed to the New York Stock Exchange ("NYSE") and NYSE Amex that execute in the opening auction. This brings the rate in line with the current rate charged for PO Orders routed to the NYSE or NYSE Amex that execute in the closing auction, and is applicable to all tiered and basic rate pricing levels. The Exchange further proposes to charge \$0.0007 per share for orders executed in the Opening or Market Order Auction in NYSE Arca primary listed securities. This brings the rate in line with the current rate charged for MOC and LOC orders executed in the Closing Auction in NYSE Arca primary listed securities, and is applicable to all tiered and basic rate pricing levels.

Finally, the Exchange proposes to clarify that the rebate paid to Lead Market Makers for orders that provide liquidity to the Book will only apply to displayed liquidity. This is consistent with the current practice and simply adds clarity to the Schedule.

The Exchange believes the proposed fees are reasonable and equitable in that

they apply uniformly to all ETP Holders. The proposed changes will become operative on October 1, 2009.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Securities Exchange Act of 1934 (the "Act"),⁶ in general, and Section 6(b)(4) of the Act,⁷ in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees, and other charges among its members and other persons using its facilities. The proposed rates are part of the Exchange's continued effort to attract and enhance participation on the Exchange, by offering attractive rebates for liquidity providers and volume-based incentives. The Exchange believes that the proposed changes to the Schedule are equitable in that they apply uniformly to our Users.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A)⁸ of the Act and subparagraph (f)(2) of Rule 19b-4⁹ thereunder, because it establishes a due, fee, or other charge imposed by NYSE Arca on its members.

At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing,

including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an e-mail to rule-comments@sec.gov. Please include File Number SR-NYSEArca-2009-88 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-NYSEArca-2009-88. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NYSEArca-2009-88 and should be submitted on or before November 12, 2009.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁰

Florence E. Harmon,
Deputy Secretary.

[FR Doc. E9-25429 Filed 10-21-09; 8:45 am]

BILLING CODE 8011-01-P

⁶ 15 U.S.C. 78f(b).

⁷ 15 U.S.C. 78f(b)(4).

⁸ 15 U.S.C. 78s(b)(3)(A).

⁹ 17 CFR 240.19b-4(f)(2).

¹⁰ 17 CFR 200.30-3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-60836; File No. SR-FINRA-2009-060]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing of Proposed Rule Change To Amend FINRA Rule 8210 (Provision of Information and Testimony and Inspection and Copying of Books)

October 16, 2009.

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 September 10, 2009, 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. 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 amend FINRA Rule 8210 to clarify the scope of the rule and to clarify certain issues with regard to service of requests made pursuant to the rule.

The text of the proposed rule change is below. Proposed new language is in *italics*; proposed deletions are in brackets.

* * * * *

8200. INVESTIGATIONS

8210. Provision of Information and Testimony and Inspection and Copying of Books

(a) Authority of Adjudicator and FINRA Staff

For the purpose of an investigation, complaint, examination, or proceeding authorized by the FINRA By-Laws or rules, an Adjudicator or FINRA staff shall have the right to:

(1) Require a member, person associated with a member, or *any other* person subject to FINRA’s jurisdiction to provide information orally, in writing, or electronically (if the requested information is, or is required to be, maintained in electronic form) and to testify at a location specified by FINRA staff, under oath or affirmation administered by a court reporter or a notary public if requested, with respect

to any matter involved in the investigation, complaint, examination, or proceeding; and

(2) Inspect and copy the books, records, and accounts of such member or person with respect to any matter involved in the investigation, complaint, examination, or proceeding *that is in such member’s or person’s possession, custody or control.*

(b) through (c) No Change.

(d) Notice

A notice under this Rule shall be deemed received by the member or *currently or formerly registered* person to whom it is directed by mailing or otherwise transmitting the notice to the last known business address of the member or the last known residential address of the person as reflected in the Central Registration Depository. *With respect to a person who is currently associated with a member in an unregistered capacity, a notice under this Rule shall be deemed received by the person by mailing or otherwise transmitting the notice to the last known business address of the member as reflected in the Central Registration Depository. With respect to a person subject to FINRA’s jurisdiction who was formerly associated with a member in an unregistered capacity, a notice under this Rule shall be deemed received by the person upon personal service, as set forth in Rule 9134(a)(1).*

If the Adjudicator or FINRA staff responsible for mailing or otherwise transmitting the notice to the member or person has actual knowledge that the address in the Central Registration Depository is out of date or inaccurate, then a copy of the notice shall be mailed or otherwise transmitted to:

(1) The last known business address of the member or the last known residential address of the person as reflected in the Central Registration Depository; and

(2) Any other more current address of the member or the person known to the Adjudicator or FINRA staff who is responsible for mailing or otherwise transmitting the notice.

If the Adjudicator or FINRA staff responsible for mailing or otherwise transmitting the notice to the member or person knows that the member or person is represented by counsel regarding the investigation, complaint, examination, or proceeding that is the subject of the notice, then the notice shall be served upon counsel by mailing or otherwise transmitting the notice to the counsel in lieu of the member or person, and any notice served upon counsel shall be deemed received by the member or person.

(e) through (f) No Change.

* * * * *

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

FINRA Rule 8210 (Provision of Information and Testimony and Inspection and Copying of Books) confers on FINRA staff the authority to compel a member, person associated with a member, or other person over whom FINRA has jurisdiction, to produce documents, provide testimony, or supply written responses or electronic data in connection with an investigation, complaint, examination or adjudicatory proceeding. The proposed rule change would clarify the scope of FINRA’s authority in this regard, specify the method of service for certain unregistered persons under the rule, and authorize service on attorneys who are representing clients, as described more fully below.

The rule applies to all members, associated persons, and other persons over which FINRA has jurisdiction, including former associated persons subject to FINRA’s jurisdiction as described in the FINRA By-Laws.³ FINRA Rule 8210(c) provides that a member’s or associated person’s failure to provide information or testimony or to permit an inspection and copying of books, records, or accounts is a violation of the rule.

Information in a Member’s or Person’s Possession, Custody or Control

FINRA Rule 8210(a)(2) currently provides that FINRA staff shall have the right to inspect and copy the books, records and accounts of all applicable members and persons with respect to any matter involved in the investigation, complaint, examination or proceeding. The proposed rule change would clarify

³ See FINRA By-Laws, Article V, Section 4(a) (Retention of Jurisdiction).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

that the information must be in the member's or person's "possession, custody or control."⁴ This language parallels the Federal Rules of Civil Procedure regarding document requests and subpoenas for documents.⁵

Notice to Associated but Unregistered Persons

FINRA Rule 8210 addresses the legal concept of service of a written request by using the term "notice" of a request. Currently, FINRA Rule 8210(d) states that notice shall be deemed received by the member or associated person when a copy of the notice is mailed or otherwise transmitted to the last known relevant address as reflected in the Central Registration Depository ("CRD®"). The CRD system contains information concerning registered members and persons,⁶ but in most instances it does not contain information concerning unregistered persons who are or were associated with a member.⁷

Although not routine, some investigations require FINRA examiners or investigators to request information from persons currently or formerly associated with a member in an unregistered capacity.⁸ The current rule

⁴In using the word "control," in addition to possession and custody, FINRA intends to require members or persons covered by the rule to provide, for example, records that they have the legal right, authority, or ability to obtain upon demand. See *Camden Iron & Metal v. Marubeni Am. Corp.*, 138 F.R.D. 438, 441 (D.N.J. 1991) ("Federal courts construe 'control' very broadly under [Federal] Rule [of Civil Procedure] 34."). Moreover, the proposed addition of "possession, custody or control" will address questions that have arisen in litigation regarding the scope of the rule. See, e.g., *In re: Jay Alan Ochanpaugh*, Securities Exchange Act Release No. 54363 (August 25, 2006).

⁵ See Fed. R. Civ. P. 34 and 35.

⁶Indeed, members and registered persons have an affirmative duty to update CRD with their current address for at least two years after they have had their registration terminated. See *Notice to Members 99-77* (noting that FINRA requests for information and disciplinary complaints issued during the period of FINRA's retained jurisdiction will be mailed to a person's last address in FINRA's records).

⁷In some limited instances, CRD may contain information concerning unregistered associated persons who were required to submit information, including fingerprint information, to CRD in connection with their employment.

⁸Persons associated with a member who are unregistered may include persons exempt from registration, e.g., those whose functions are solely and exclusively clerical or ministerial; those whose functions are related solely and exclusively to the member's need for nominal corporate officers or for capital participation; and those whose functions are related solely and exclusively to transactions in municipal securities, transactions in commodities, or transactions in security futures (provided they are registered with a registered futures association). See, e.g., NASD Rule 1060(a). For purposes of FINRA Rule 8210, unregistered persons associated with a member may also include direct owners and executive officers listed in Schedule A of Form BD

is unclear as to what would constitute proper notice on such persons for whom information is not available in CRD. The proposed rule change would explicitly address the methods by which notice will be deemed received by persons currently or formerly associated with a member in an unregistered capacity.

With respect to unregistered persons currently associated with a member, the proposed rule change would provide that notice shall be deemed received by mailing or otherwise transmitting the notice to the last known business address of the member as reflected in CRD. In addition, the proposed rule change would retain the provision that, if FINRA staff responsible for transmitting the notice has actual knowledge that the member's address provided through CRD is out of date or inaccurate, then a copy of the notice must be transmitted to both the address provided through CRD, as well as any more current address known to FINRA staff.

With respect to unregistered persons formerly associated with a member, the proposed rule change would provide that notice shall be deemed received upon personal service, which is defined as set forth in FINRA Rule 9134(a)(1).⁹ FINRA Rule 9134(a)(1) is based on traditional concepts for serving a summons under Rule 4 of the Federal Rules of Civil Procedure.

Notice to Members and Persons Represented by Counsel

The proposed rule change would amend FINRA Rule 8210 to explicitly address issues of service on members or persons that are known to be represented by counsel. Currently, the rule does not explicitly permit FINRA staff to serve notice on a member's or person's counsel in situations in which FINRA staff knows that the member or person is represented by counsel regarding the matter in question. The proposed rule change would allow FINRA staff to recognize that counsel can act as an authorized agent on behalf of a member or person. It would provide that, if FINRA staff knows that a member or person is represented by counsel regarding the matter in question, then notice shall be provided

of a member whose job functions do not otherwise require them to register with FINRA. See FINRA By-Laws, Article I(rr) (definition of "person associated with a member").

⁹FINRA Rule 9134(a)(1) provides as follows:

Personal service may be accomplished by handing a copy of the papers to the person required to be served; leaving a copy at the person's office with an employee or other person in charge thereof; or leaving a copy at the person's dwelling or usual place of abode with a person of suitable age and discretion then residing therein.

to counsel rather than to the member or person. The proposed rule change would harmonize FINRA's rule in this regard with Codes of Professional Conduct in many states regarding service on counsel.¹⁰

FINRA will announce the effective date of the proposed rule change in a *Regulatory Notice* to be published no later than 60 days following Commission approval. The effective date will be 30 days following publication of the *Regulatory Notice* announcing Commission approval.

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. Vigorous enforcement of the rule has been described as "help[ing to] ensure the continued strength of the self-regulatory system—and thereby enhanc[ing] the integrity of the securities markets and protect[ing] investors."¹² FINRA believes that the proposed rule change will clarify the scope of its authority regarding requests pursuant to FINRA Rule 8210, and explicitly provide FINRA staff with a method to effectively serve notice on persons currently or formerly associated with a member in an unregistered capacity, as well as to members and persons represented by counsel. Thus, FINRA believes the proposed rule change will benefit its enforcement program by providing clarity regarding both scope of requests and service of requests pursuant to FINRA Rule 8210, consistent with the statutory provisions noted above.

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

¹⁰ See, e.g., American Bar Association model Rule of Professional Conduct 4.2 ("ABA Rule 4.2"). ABA Rule 4.2 provides as follows:

[i]n representing a client, a lawyer shall not communicate about the subject of the representation with a person the lawyer knows to be represented by another lawyer in the matter, unless the lawyer has the consent of the other lawyer or is authorized to do so by law or a court order.

Many states have rules regarding communication with a person represented by counsel that are based on ABA Rule 4.2.

¹¹ 15 U.S.C. 78o-3(b)(6).

¹² *In re: Charles C. Fawcett, IV*, Securities Exchange Act Release No. 56770 (November 8, 2007).

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

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the *Federal Register* or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve such proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an e-mail to rule-comments@sec.gov. Please include File Number SR-FINRA-2009-060 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-2009-060. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the

proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of 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-2009-060 and should be submitted on or before November 12, 2009.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹³

Florence E. Harmon,
Deputy Secretary.

[FR Doc. E9-25431 Filed 10-21-09; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-60835; File No. SR-FINRA-2009-055]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Order Approving Proposed Rule Change To Adopt FINRA Rules 5210 (Publication of Transactions and Quotations) and 5220 (Offers at Stated Prices) Into the Consolidated Rulebook

October 16, 2009.

On August 18, 2009, the Financial Industry Regulatory Authority, Inc. ("FINRA") (f/k/a National Association of Securities Dealers, Inc. ("NASD")) filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")¹ and Rule 19b-4 thereunder,² a proposed rule change to adopt NASD Rule 3310 (Publication of Transactions and Quotations), NASD Rule 3320 (Offers at Stated Prices), IM-3310 (Manipulative and Deceptive Quotations) and IM-3320 (firmness of Quotations) as FINRA rules in the consolidated FINRA rulebook without material changes. The proposed rule change would combine NASD Rule

3310 and IM-3310 into FINRA Rule 5210 and would combine NASD Rule 3320 and IM-3320 into FINRA Rule 5220 in the consolidated FINRA rulebook. The proposed rule change was published for comment in the **Federal Register** on September 11, 2009.³ The Commission received no comments on the proposal. This order approves the proposed rule change.

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities association.⁴ In particular, the Commission finds that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,⁵ which requires, among other things, that FINRA rules 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.

The Commission believes that the proposed rule change is designed to protect investors and promote the maintenance of fair, orderly and efficient markets by prohibiting a member from publishing a report of any transaction unless the member believes that it was a bona fide purchase or sale of the security and from "backing away" from its quotations. In approving the proposed rule change, the Commission notes that FINRA is adopting NASD Rule 3310 (Publication of Transactions and Quotations), NASD Rule 3320 (Offers at Stated Prices), IM-3310 (Manipulative and Deceptive Quotations) and IM-3320 (firmness of Quotations) as FINRA rules in the consolidated FINRA rulebook without material changes. The Commission also notes FINRA's representation that it will remind its members of their obligation to have in place a supervisory system and written procedures reasonably designed to ensure the accuracy and integrity of information entered into order-routing execution systems, as further addressed in its Notice to Members 04-66, in a regulatory notice announcing the approval of the proposed rule change.⁶

³ See Securities Exchange Act Release No. 60613 (September 2, 2009), 74 FR 46814.

⁴ In approving this proposal, the Commission has considered the proposed rule's impact on efficiency, competition and capital formation. See 15 U.S.C. 78c(f).

⁵ 15 U.S.C. 78o-3(b)(6).

⁶ See e-mail from Racquel L. Russell, Assistant General Counsel, FINRA, to Mia Zur, Special Counsel, and Steve Varholik, Special Counsel, Division of Trading and Markets, Commission, October 13, 2009.

¹³ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,⁷ that the proposed rule change (SR-FINRA-2009-055) be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁸

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E9-25430 Filed 10-21-09; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-60833; File No. SR-NYSEArca-2009-91]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending the Dates of the Quarterly Expansion of the Penny Pilot Program for Options

October 16, 2009.

Pursuant to Section 19(b)(1)¹ of the Securities Exchange Act of 1934 (the "Act")² and Rule 19b-4 thereunder,³ notice is hereby given that on October 13, 2009, NYSE Arca, Inc. ("NYSE Arca" or "Exchange") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the dates of the quarterly expansion of the Penny Pilot Program for Options ("Penny Pilot" or "Pilot"). There are no changes to the Rule text. A copy of this filing is available on the Exchange's Web site at <http://www.nyse.com>, at the Exchange's principal office and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change

and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

NYSE Arca proposes to amend the dates of the quarterly expansion of the Pilot.⁴

The Exchange proposes to add 75 issues to the Pilot on November 2, 2009; February 1, 2010; May 3, 2010; and August 2, 2010. The issues to be added on November 2, 2009 will be based on the most actively traded multiply listed issues for the six month period from April 1, 2009 through September 30, 2009. The issues to be added on February 1, 2010 will be based on the most actively traded multiply listed issues for the six month period from July 1, 2009 through December 31, 2009. The issues to be added on May 3, 2010 will be based on the most actively traded multiply listed issues for the six month period from October 1, 2009 through March 31, 2010. The issues to be added on August 2, 2010 will be based on the most actively traded multiply listed issues for the six month period from January 1, 2010 through June 30, 2010.

The purpose of the date adjustment for the Pilot is because of concerns raised by NYSE Arca Option Trading Permit ("OTP") Holders and Firms. After the Exchange received approval to extend and expand the Pilot, many OTP Holders and Firms expressed concern that a date that did not correspond with the start of a calendar month would interfere with month end processing for billing and cost allocation purposes.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with and furthers the objectives of Section 6(b)(5) of the Act, in that it is designed to promote just and equitable principles of trade, remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest. As described herein, the Exchange is simply revising the dates of the

quarterly expansion of the Pilot, by one week, so as to avoid problems for OTP Holders and Firms regarding their month end processing.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act⁵ and Rule 19b-4(f)(6) thereunder.⁶ Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act⁷ and Rule 19b-4(f)(6)(iii) thereunder.⁸

A proposed rule change filed under Rule 19b-4(f)(6) normally does not become operative prior to 30 days after the date of the filing.⁹ However, pursuant to Rule 19b-4(f)(6)(iii),¹⁰ the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Commission believes that waiving the 30-day operative delay is consistent with the protection of

⁵ 15 U.S.C. 78s(b)(3)(A)(iii).

⁶ 17 CFR 240.19b-4(f)(6).

⁷ 15 U.S.C. 78s(b)(3)(A).

⁸ 17 CFR 240.19b-4(f)(6)(iii).

⁹ 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change along with a brief description and 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. The Exchange has satisfied this pre-filing requirement.

¹⁰ 17 CFR 240.19b-4(f)(6)(iii).

⁷ 15 U.S.C. 78s(b)(2).

⁸ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.

⁴ See Exchange Act Release No. 60711 (September 23, 2009), 74 FR 49419 (September 28, 2009) (order approving SR-NYSEArca-2009-44).

investors and the public interest because doing so will accommodate the administrative concerns of certain market participants while still allowing the Exchange to expand the Pilot in a manner that is consistent with the Commission's prior approval of the extension and expansion of the Pilot.¹¹ Furthermore, the proposal will delay the expansion of the Pilot by only one week and will therefore facilitate expansion of the Pilot in a timely manner. Accordingly, the Commission designates the proposed rule change as operative upon filing with the Commission.¹²

At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an e-mail to rule-comments@sec.gov. Please include File Number SR-NYSEArca-2009-91 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-NYSEArca-2009-91. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule

change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the self-regulatory organization. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NYSEArca-2009-91 and should be submitted on or before November 12, 2009.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹³

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E9-25428 Filed 10-21-09; 8:45 am]

BILLING CODE 8011-01-P

SOCIAL SECURITY ADMINISTRATION

[Docket No. SSA-2009-0070]

Future Systems Technology Advisory Panel Meeting

AGENCY: Social Security Administration (SSA).

ACTION: Notice of fifth panel meeting; correction to starting time on November 5, 2008.

DATES: November 5, 2009, 10 a.m.–5 p.m. and November 6, 2009, 8:30 a.m.–12 p.m.

Location: Omni Shoreham Hotel.

ADDRESSES: 2500 Calvert Street Northwest Washington, District of Columbia 20008.

SUPPLEMENTARY INFORMATION:

Type of Meeting: The meeting is open to the public.

Purpose: The Panel, under the Federal Advisory Committee Act of 1972, as amended, (hereinafter referred to as "the FACA") shall report to and provide the Commissioner of Social Security independent advice and recommendations on the future of systems technology and electronic

services at the agency five to ten years into the future. The Panel will recommend a road map to aid SSA in determining what future systems technologies may be developed to assist in carrying out its statutory mission. Advice and recommendations can relate to SSA's systems in the area of Internet application, customer service, or any other arena that would improve SSA's ability to serve the American people.

Agenda: The Panel will meet on Thursday, November 5, 2009 from 10 a.m. until 5 p.m. and Friday, November 6, 2009 from 8:30 a.m. to 12 p.m. The agenda will be available on the Internet at <http://www.ssa.gov/fstap/index.htm> or available by e-mail or fax on request, one week prior to the starting date.

During the fifth meeting, the Panel may have experts address items of interest and other relevant topics to the Panel. This additional information will further the Panel's deliberations and the effort of the Panel subcommittees.

Public comments will be heard on Thursday, November 5, 2009, from 4:30 p.m. until 5 p.m. Individuals interested in providing comments in person should contact the Panel staff as outlined below to schedule a time slot. Members of the public must schedule a time slot in order to comment. In the event public comments do not take the entire scheduled time period, the Panel may use that time to deliberate or conduct other Panel business. Each individual providing public comment will be acknowledged by the Chair in the order in which they are scheduled to testify and is limited to a maximum five-minute, verbal presentation. In addition to or in lieu of public comments provided in person, written comments may be provided to the panel for their review and consideration. Comments in written or oral form are for informational purposes only for the Panel. Public comments will not be specifically addressed or receive a written response by the Panel.

For hearing impaired persons and those in need of sign language services please contact the Panel staff as outlined below at least 10 business days prior to the meeting so that timely arrangements can be made to provide this service.

Contact Information: Records are kept of all proceedings and will be available for public inspection by appointment at the Panel office. Anyone requiring information regarding the Panel should contact the staff by:

Mail addressed to SSA, Future Systems Technology Advisory Panel, Room 800, Altmeyer Building, 6401 Security Boulevard, Baltimore, MD 21235-0001; telephone at 410-966-

¹¹ See *supra* note 4.

¹² For purposes only of waiving the operative delay for this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

¹³ 17 CFR 200.30-3(a)(12).

4150; fax at 410-965-0201; or e-mail to FSTAP@ssa.gov.

Dated: October 16, 2009.

Dianne L. Rose,

Designated Federal Officer, Future Systems Technology Advisory Panel.

[FR Doc. E9-25391 Filed 10-21-09; 8:45 am]

BILLING CODE 4191-02-P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Generalized System of Preferences (GSP): Notice Regarding the 2009 Annual Product Review for Acceptance of Product Petitions

AGENCY: Office of the United States Trade Representative.

ACTION: Notice.

SUMMARY: The Office of the United States Trade Representative (USTR) received petitions in connection with the 2009 GSP Annual Review to modify the list of products that are eligible for duty-free treatment under the GSP program ("2009 GSP Annual Product Review"). This Notice announces the petitions accepted for review to add or remove products from the list of products eligible for duty-free treatment under GSP and sets forth the review schedule for comment and public hearings, for requesting participation in the hearings, for submitting pre-hearing and post-hearing briefs, and for commenting on the U.S. International Trade Commission's (USITC) report on probable economic effects. The list of accepted petitions is available at: <http://www.ustr.gov/trade-topics/trade-development/preference-programs/generalized-system-preference-gsp/current-review-1> [2009 Annual Review] and at Regulations.gov, Docket Number USTR-2009-0036.

FOR FURTHER INFORMATION CONTACT: Tameka Cooper, GSP Program, Office of the United States Trade Representative, 1724 F Street, NW., Washington, DC 20508. The telephone number is (202) 395-6971, the fax number is (202) 395-2961, and the e-mail address is Tameka_Cooper@ustr.eop.gov.

DATES: The GSP regulations (15 CFR Part 2007) provide the schedule of dates for conducting an annual review unless otherwise specified in a **Federal Register** notice. The schedule for the 2009 GSP Annual Product Review is set forth below. Notification of any other changes will be given in the **Federal Register**.

November 6, 2009—Due date for submission of pre-hearing briefs and requests to appear at the GSP

Subcommittee Public Hearing on the 2009 GSP Annual Product Review that include the name, address, telephone, fax, e-mail address and organization of witnesses for accepted product petitions.

November 17, 2009—Due date for submission of new petitions to grant waivers to CNLs for products exceeding the competitive need limitations (CNLs) in 2009 and for determinations of products not produced in the United States as of January 1, 1995.

November 19, 2009—GSP Subcommittee Public Hearing on all product petitions accepted for the 2009 GSP Annual Product Review in Rooms 1 and 2, 1724 F St., NW., Washington, DC 20508, beginning at 9:30 a.m.

December 3, 2009—Due date for submission of product petition post-hearing briefs.

February 2010—The USITC is scheduled to publish a public version of the report providing advice on the potential impacts on U. S. industry and consumers based on the product petitions accepted in the 2009 GSP Annual Product Review. Comments on the USITC report on these products is due 10 calendar days after the date of USITC's publication of the public version of the report.

June 30, 2010—Modifications to the list of articles eligible for duty-free treatment under the GSP resulting from the 2009 Annual Product Review will be announced on or about June 30, 2010, in the **Federal Register**, and any changes will take effect on the effective date announced. Notification of any changes to this date will be given in the **Federal Register**.

SUPPLEMENTARY INFORMATION: The GSP program provides for the duty-free importation of designated articles when imported from designated beneficiary developing countries. The GSP program is authorized by Title V of the Trade Act of 1974 (19 U.S.C. 2461, *et seq.*), as amended (the "1974 Act"), and is implemented in accordance with Executive Order 11888 of November 24, 1975, as modified by subsequent Executive Orders and Presidential Proclamations.

Petitions Requesting Modifications of Product Eligibility

In a **Federal Register** notice dated May 28, 2009, USTR announced that the deadline for the filing of product petitions, other than those requesting waivers of "competitive need limitations" (CNLs), country practice petitions for the 2009 GSP Annual Review was June 24, 2009 (74 FR 25605). The deadline for the filing of product petitions requesting waivers of

the CNLs and determinations that any eligible products were not produced in the United States as of January 1, 1995, was announced to be November 17, 2009.

The petitions that were received requested 164 modifications in the list of GSP-eligible products by adding new products for eligibility from all GSP beneficiaries, by removing products from eligibility when imported from specific GSP-eligible countries, or other changes. The interagency GSP Subcommittee of the Trade Policy Staff Committee (TPSC) has reviewed the product petitions, and the TPSC has decided to accept for review the product petitions listed in "List of Petitions Accepted in the 2009 GSP Annual Product Review" posted on the USTR Web site and available on Regulations.gov docket number USTR-2009-0036. That list sets forth, for each type of change requested: the case number, the Harmonized Tariff Schedule of the United States (HTS) subheading number, a brief description of the product (see the HTS for an authoritative description available on the U.S. International Trade Commission Web site <http://www.usitc.gov/tata/hts/>), and the petitioner for each petition included in this review. Acceptance of a petition for review does not indicate any opinion with respect to the disposition on the merits of the petition. Acceptance indicates only that the listed petitions have been found eligible for review by the TPSC and that such review will take place.

The GSP Subcommittee of the TPSC invites testimony at the public hearing, based on receipt of requests to testify, and comments in support of or in opposition to any petition which has been accepted thus far for the 2009 GSP Annual Product Review. Submissions should comply with 15 CFR Part 2007, except as modified below. All submissions should identify the subject article(s) in terms of the case number and eight digit HTSUS subheading number, if applicable, as shown in the "List of Petitions Accepted in the 2009 GSP Product Annual Review" available at: <http://www.ustr.gov/trade-topics/trade-development/preference-programs/generalized-system-preference-gsp/current-review-1> [2009 Annual Review].

Requirements for Submissions

Submissions in response to this notice (including requests to testify, written comments, and pre-hearing and post-hearing briefs), with the exception of business confidential submissions, must be submitted electronically by 5 p.m.,

Tuesday, November 6, 2009, or by 5 p.m., Thursday, December 3, 2009 (post hearing briefs only) using <http://www.regulations.gov>, docket number USTR-2009-0036. Instructions for submitting business confidential versions are provided below. Hand-delivered submissions will not be accepted. Submissions must be submitted in English to the Chairman of the GSP Subcommittee, Trade Policy Staff Committee, by the applicable deadlines set forth in this notice.

To make a submission using <http://www.regulations.gov>, enter docket number USTR-2009-0036 on the home page and click "Search." The site will provide a search-results page listing all documents associated with this docket. Locate the reference to this notice by selecting "Notices" under "Document Type". In the results table below, click on the "Send a Comment" link that corresponds to this notice. Follow the instructions given on the screen to submit the comment. The <http://www.regulations.gov> Web site offers the option of providing comments by filling in a "Type Comment" field or by attaching a document. While both options are acceptable, USTR prefers submissions in the form of an attachment.

Comments must be in English, with the total submission not to exceed 30 single-spaced standard letter-size pages in 12-point type, including attachments. Any data attachments to the submission should be included in the same file as the submission itself, and not as separate files.

Any person or party making a submission is strongly advised to review the GSP regulations and GSP Guidebook (available at: <http://www.ustr.gov/trade-topics/trade-development/preference-programs/generalized-system-preference-gsp/gsp-program-inf>)

Business Confidential Submissions

Persons wishing to submit business confidential information must submit that information by electronic mail to FR0807@ustr.eop.gov. Business confidential submissions will not be accepted at <http://www.regulations.gov>. For any document containing business confidential information submitted as a file attached to an e-mail transmission, the file name of the business confidential version should begin with the characters "BC." The "BC" should be followed by the name of the party (government, company, union, association, etc.) that is making the submission.

If a comment contains business confidential information that the submitter wishes to protect from public

disclosure, the confidential submission must be marked "BUSINESS CONFIDENTIAL" at the top and bottom of each page. The submitter must provide a written explanation of why the information should be protected in accordance with 15 CFR 2007.7(b). In addition, the submission must be accompanied by a non-confidential version that indicates, with asterisks, where confidential information was redacted or deleted. The top and bottom of each page of the non-confidential version must be marked either "PUBLIC VERSION" or "NON-CONFIDENTIAL". The file name of the public version should begin with the characters "P". The "P" should be followed by the name of the party (government, company, union, association, etc.) that is making the submission.

Business confidential comments that are submitted without the required markings or that are not accompanied by a properly marked non-confidential version as set forth above may not be accepted or may be treated as public documents. A copy of the public version will be posted on [Regulations.gov](http://www.regulations.gov).

Notice of Public Hearing

A hearing will be held by the GSP Subcommittee of the TPSC on Thursday, November 19, 2009, for product petitions accepted for the 2009 GSP Annual Review (i.e., for product petitions other than those requesting CNL waivers) beginning at 9:30 a.m. at the Office of the U.S. Trade Representative, Rooms 1 and 2, 1724 F St., NW., Washington, DC 20508. The hearing will be open to the public, and a transcript of the hearing will be made available for public inspection or can be purchased from the reporting company. No electronic media coverage will be allowed.

All interested parties wishing to make an oral presentation at the hearing must submit, following the above "Requirements for Submissions", the name, address, telephone number, facsimile number, and e-mail address (if available), of the witness(es) representing their organization to Marideth Sandler, Executive Director of the GSP Program by 5 p.m., Friday, November 6, 2009. Requests to present oral testimony in connection with the public hearing must be accompanied by a written brief or statement, in English, and also must be received by 5 p.m., Friday, November 6, 2009. Oral testimony before the GSP Subcommittee will be limited to five-minute presentations that summarize or supplement information contained in briefs or statements submitted for the record. Post-hearing briefs or statements

will be accepted if they conform with the regulations cited above and are submitted, in English, by 5 p.m., Thursday, December 3, 2009, following the "Requirements for Submissions" above. Parties not wishing to appear at the public hearing may submit pre-hearing briefs or statements, in English, by 5 p.m., November 6, 2009, and post-hearing written briefs or statements, in English, by 5 p.m., December 3, 2009, also in accordance with the "Requirements for Submissions" above.

Receipt of Advice From the USITC

With respect to petitions to add or remove articles from the "List of Product Petitions Accepted in the 2009 GSP Annual Review," and in accordance with sections 503(d)(1)(A) of the 1974 Act and the authority delegated by the President, pursuant to section 332(g) of the Tariff Act of 1930, the U.S. Trade Representative has requested that the USITC provide its advice on the probable economic effect of such additions or removals on U.S. industries producing like or directly competitive articles and on consumers. Comments by interested persons on the USITC Report prepared as part of the product review other than those requesting CNL waivers should be submitted by 5 p.m., 10 calendar days after the date of USITC publication of the public version of its report.

Marideth J. Sandler,

Executive Director, Generalized System of Preferences (GSP) Program, Office of the U.S. Trade Representative.

[FR Doc. E9-25459 Filed 10-21-09; 8:45 am]

BILLING CODE 3190-W0-P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Docket No. AB-6 (Sub-No. 469X)]

BNSF Railway Company— Abandonment Exemption—in Pierce County, WA

BNSF Railway Company (BNSF) filed a notice of exemption under 49 CFR part 1152 subpart F—*Exempt Abandonments* to abandon a 1.56-mile line of railroad between milepost 0.59, and milepost 2.15, in Tacoma, Pierce County, WA. The line traverses United States Postal Service Zip Code 98402.

BNSF has certified that: (1) No local traffic has been handled to or from any customer over the rail line for at least 2 years; (2) all overhead traffic has been rerouted; (3) no formal complaint filed by a user of rail service on the line (or by a state or local government entity

acting on behalf of such user) regarding cessation of service over the line either is pending with the Board or with any U.S. District Court or has been decided in favor of complainant within the 2-year period; and (4) the requirements at 49 CFR 1105.7 (environmental report), 49 CFR 1105.8 (historic report), 49 CFR 1105.11 (transmittal letter), 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to this exemption, any employee adversely affected by the abandonment shall be protected under *Oregon Short Line R. Co.—Abandonment—Goshen*, 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 November 21, 2009, 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 November 2, 2009. Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by November 12, 2009, with: Surface Transportation Board, 395 E Street, SW., Washington, DC 20423–0001.

A copy of any petition filed with the Board should be sent to BNSF's representative: Kristy Clark, General Attorney, BNSF Railway Company, 2500 Lou Menk Drive, AOB–3, Fort Worth, TX 76131.

If the verified notice contains false or misleading information, the exemption is void *ab initio*.

BNSF has filed environmental and historic reports which address the effects, if any, of the abandonment on the environment and historic resources.

SEA will issue an environmental assessment (EA) by October 27, 2009. Interested persons may obtain a copy of the EA by writing to SEA (Room 1100, Surface Transportation Board, Washington, DC 20423–0001) or by calling SEA, at (202) 245–0305. Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at 1–800–877–8339. Comments on environmental and historic preservation matters must be filed within 15 days after the EA becomes available to the public.

Environmental, historic preservation, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Pursuant to the provisions of 49 CFR 1152.29(e)(2), BNSF 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 BNSF's filing of a notice of consummation by October 22, 2010, 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 <http://www.stb.dot.gov>.

Decided: October 19, 2009.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Kulunie L. Cannon,
Clearance Clerk.

[FR Doc. E9–25432 Filed 10–21–09; 8:45 am]

BILLING CODE 4915–01–P

ACTION: List of applications for special permits.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, special permits from the Department of Transportation's Hazardous Material Regulations (49 CFR Part 107, Subpart B), notice is hereby given that the Office of Hazardous Materials Safety has received the application described herein. Each mode of transportation for which a particular special permit is requested is indicated by a number in the "Nature of Application" portion of the table below as follows: 1—Motor vehicle, 2—Rail freight, 3—Cargo vessel, 4—Cargo aircraft only, 5—Passenger-carrying aircraft.

DATES: Comments must be received on or before November 23, 2009.

ADDRESS COMMENTS TO: Record Center, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the special permit number.

FOR FURTHER INFORMATION CONTACT: Copies of the applications are available for inspection in the Records Center, East Building, PHH–30, 1200 New Jersey Avenue Southeast, Washington DC or at <http://regulations.gov>.

This notice of receipt of applications for special permit is published in accordance with Part 107 of the Federal hazardous materials transportation law (49 U.S.C. 5117(b); 49 CFR 1.53(b)).

Issued in Washington, DC, on October 7, 2009.

Delmer F. Billings,

Director, Office of Hazardous Materials, Special Permits and Approvals.

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

Office of Hazardous Materials Safety; Notice of Application for Special Permits

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

NEW SPECIAL PERMITS

Application No.	Docket No.	Applicant	Regulations(s) affected	Nature of special permits thereof
14910–N	Drug & Laboratory Disposal, Inc., Plainwell, MI.	49 CFR 178.503	To authorize the transportation in commerce of UN 1H2 plastic drums that are intended to be non-reusable as the outer packaging for lab packs. (modes 1, 2, 3)

¹ The Board will grant a stay if an informed decision on environmental issues (whether raised by a party or by the Board's Section of Environmental Analysis (SEA) in its independent investigation) cannot be made before the

exemption's effective date. *See Exemption of Out-of-Service 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 currently is set at \$1,500. *See* 49 CFR 1002.2(f)(25).

NEW SPECIAL PERMITS—Continued

Application No.	Docket No.	Applicant	Regulations(s) affected	Nature of special permits thereof
14911-N		ITW Sexton, Decatur, AL	49 CFR 173.304a	To authorize the manufacture, marking and sale of a non-DOT specification cylinder to be used for the transportation in commerce of certain Division 2.2 materials. (modes 1, 2, 3, 4)
14912-N		ITW Sexton, Decatur, AL	49 CFR 173.304a and 173.306(a)(3)(ii).	To authorize the manufacture, marking and sale of a non-DOT specification container to be used for the transportation in commerce of certain Division 2.2 materials. (modes 1, 2, 3, 4)
14913-N		Air Products and Chemicals, Inc., Allentown, PA.	49 CFR 171.23(a)(3)	To authorize the one-time transportation in commerce of 115 non-DOT specification cylinders containing arsine and arsine mixtures by dedicated motor vehicle. (mode 1)
14914-N		The Boeing Company, St. Louis, MO.	49 CFR 173.62	To authorize the transportation in commerce of a T-45 canopy containing a Division 1.4S explosive in alternative packaging. (mode 1)
14915-N		Schering-Plough, Summit, NJ	49 CFR 172.200, 172.300, 172.400 and 172.500.	To authorize the one-time, one-way transportation in commerce of a finished product from its primary production building to another location to complete product filling, packaging and shipping without shipping papers, marking, labeling or placarding. (mode 1)
14916-N		Air Products and Chemicals, Inc., Allentown, PA.	49 CFR 173.240	To authorize the transportation in commerce of an assembled electrolytic cell containing corrosive solids, toxic, n.o.s. in alternative packaging. (modes 1, 3)
14917-N		DSE Fuzing LLC, Orlando, FL	49 CFR 177.848(f)	To authorize the transportation in commerce of certain explosives by motor vehicle with alternative segregation. (mode 1)
14918-N		Aviall Services, Inc., Van Nuys, CA.	49 CFR 173.159(f) and Packing Instruction 806 of ICAO.	To authorize the transportation in commerce of nickel cadmium aircraft batteries UN2795 as non-spillable batteries when in specially designed packagings. (modes 1, 4, 5)
14919-N		TK Holdings Inc., Armada, MI	49 CFR 173.301(a) and 173.302a.	To authorize the manufacture, marking, sale and use of non-DOT specification cylinders for use in automobile safety systems. (modes 1, 2, 3, 4)
14920-N		Dapco Industries, Inc., Ridgefield, CT.	49 CFR 173.302a, 180.205, and 180.209.	To authorize the transportation in commerce of certain cylinders that have tested using ultrasonic examinations with visual external examination in lieu of hydrostatic testing and internal visual inspection. (modes 1, 2, 3, 4, 5)
14924-N		Explosive Service International Ltd., Baton Rouge, LA.	49 CFR 176.144(e), 176.145(b), 176.137(b)(7), 176.63(e), 176.83 and 176.138(b).	To authorize the transportation in commerce of certain Division 1.1D and 1.4B explosives by vessel in an alternative stowage configuration. (mode 3)

[FR Doc. E9-25277 Filed 10-21-09; 8:45 am]
 BILLING CODE 4909-60-M

ACTION: List of applications for modification of special permits.

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

Applications for Modification of Special Permit

AGENCY: Office of Hazardous Materials Safety, Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, special permits from the Department of Transportation's Hazardous Material Regulations (49 CFR part 107, subpart B), notice is hereby given that the Office of Hazardous Materials Safety has received the applications described herein. This notice is abbreviated to expedite docketing and public notice. Because the sections affected, modes of transportation, and the nature of application have been shown in earlier

Federal Register publications, they are not repeated here. Requests for modification of special permits (*e.g.* to provide for additional hazardous materials, packaging design changes, additional mode of transportation, *etc.*) are described in footnotes to the application number. Application numbers with the suffix "M" denote a modification request. These applications have been separated from the new application for special permits to facilitate processing.

DATES: Comments must be received on or before November 6, 2009.

Address Comments to: Record Center, Pipeline and Hazardous Materials Safety

Administration, U.S. Department of Transportation, Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the special permit number.

FOR FURTHER INFORMATION CONTACT: Copies of the applications are available for inspection in the Records Center, East Building, PHH-30, 1200 New Jersey Avenue, Southeast, Washington, DC or at <http://regulations.gov>.

This notice of receipt of applications for modification of special permit is published in accordance with part 107

of the Federal hazardous materials transportation law (49 U.S.C. 5117(b); 49 CFR 1.53(b)).

Issued in Washington, DC, on October 6, 2009.

Delmer F. Billings,

Director, Office of Hazardous Materials Special Permits and Approvals.

Application No.	Docket No.	Applicant	Regulation(s) affected	Nature of special permit thereof
Modification Special Permits				
14298-M	Air Products and Chemicals, Inc., Allentown, PA.	49 CFR 180.209(a) and (b).	To modify the special permit to authorize more cycle fillings of each cylinder (tube) from 300 to 600 in a 10 year period.
14523-M	Pacific Bio-Material Management, Inc., Fresno, CA.	49 CFR 173.196(b); 173.196(e)(2)(ii).	To modify the special permit to authorize the transportation of material in other than the specific make and model of the freezers described in the special permit and to change the advance notice time from 1 month to 48-72 hours.
14894-M	Department of Defense, Scott Air Force Base, IL.	49 CFR 172.10 1 Table Column (9B).	To reissue the special permit originally issued on an emergency basis to the one-time, one-way transportation in commerce of certain explosives that are forbidden for transportation by cargo only aircraft.

[FR Doc. E9-25279 Filed 10-21-09; 8:45 am]
BILLING CODE M

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA-2009-0160]

Notice of Cancellation of Public Hearing to Determine Whether Transportation Collaborative, Inc. (TCI) Has Met Notification and Remedy Requirements

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Notice of hearing cancellation.

SUMMARY: NHTSA is issuing this notice to cancel a public hearing scheduled for October 23, 2009, at 10 a.m. This public hearing was originally announced in a notice published in the **Federal Register**, 74 FR 48624, on September 23, 2009.

SUPPLEMENTARY INFORMATION: NHTSA is cancelling the October 23, 2009 public hearing to gather information on whether Transportation Collaborative, Inc. of Warwick, New York, ("TCI") had reasonably met its obligations under the National Traffic and Motor Vehicle Safety Act, as amended, to notify owners, purchasers, and dealers and/or remedy failures to comply with federal motor vehicle safety standards (FMVSS) or defects related to motor vehicle safety in fifteen (15) recalls involving vehicles built by U.S. Bus, Inc. of Suffern, New

York ("U.S. Bus"). TCI has agreed to undertake all actions necessary to carry out the fifteen (15) recalls.

FOR FURTHER INFORMATION CONTACT: Zachary Dunlap, Office of Chief Counsel, National Highway Traffic Safety Administration, 1200 New Jersey Avenue, SE., Washington, DC 20590; (202) 366-5263.

Authority: 49 U.S.C. 30118(e), 30120(e); 49 CFR 557.7; delegations of authority at 49 CFR 1.50(a), 49 CFR 501.4(a)(3), and 49 CFR 501.8.

Issued: October 19, 2009.

Claude Harris,

Director, Office of Vehicle Safety and Compliance.

[FR Doc. E9-25464 Filed 10-21-09; 8:45 am]

BILLING CODE 4910-59-P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions Oregon City Arch Bridge Rehabilitation Project; Clackamas County, OR

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of Limitations on Claims for Judicial Review of Actions by FHWA.

SUMMARY: This notice announces actions taken by the FHWA that are final within the meaning of 23 U.S.C. 139(l)(1). The actions relate to a proposed bridge rehabilitation project, Oregon City Arch Bridge Rehabilitation Project, in

Clackamas County, Oregon. This action grants approval for the project.

DATES: By this notice, the FHWA is advising the public of final agency actions subject to 23 U.S.C. 139(l)(1). A claim seeking judicial review of the Federal agency actions on the highway project will be barred unless the claim is filed on or before April 20, 2010. If the Federal law that authorizes judicial review of a claim provides a time period of less than 180 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: Michelle Eraut, Environmental Program Manager, Federal Highway Administration, 530 Center Street, NE., Suite 100, Salem, Oregon 97301, Telephone: (503) 587-4716. The Oregon City Arch Bridge Rehabilitation project categorical exclusion, re-evaluation and other project records are available upon written request from the Federal Highway Administration at the address shown above. Comments or questions concerning this proposed action and the Oregon City Arch Bridge Rehabilitation project should be directed to the FHWA at the address provided above.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the FHWA, has taken final agency action subject to 23 U.S.C. 139 (l)(1) by issuing approval for the following bridge rehabilitation project in the State of Oregon: Oregon City Arch Bridge Rehabilitation Project. The project will repair and provide improvements to the bridge deck, bridge rails and deck joints. The structure will

be cleaned, the sprayed-on gunitite exterior will be removed and repaired, the deck will be restored, existing sidewalks and rails will be removed and replaced, and illumination will be repaired and replaced. All work will be consistent with State and Federal standards for preservation of this historic structure. Approximately 1,600 square feet of pavement will be reconstructed on the Oregon City side of the bridge to repair the existing ramp approach to the bridge. The actions by the Federal agencies and the laws under which such actions were taken are described in the categorical exclusion approved February 11, 2009, the re-evaluation approved on October 15, 2009, and in other documents in the FHWA project records. The re-evaluation, categorical exclusion and other project records are available by contacting the FHWA at the address provided above. This notice applies to all Federal agency decisions as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. *General*: National Environmental Policy Act (NEPA) [42 U.S.C. 4321–4347]; Federal-Aid Highway Act [23 U.S.C. 109 and 23 U.S.C. 128].

2. *Air*: Clean Air Act [42 U.S.C. 7401–7671(q)].

3. *Land*: Section 4(f) of the Department of Transportation Act of 1966 [23 U.S.C. 138 and 49 U.S.C. 303]; Section 6(f) of the Land and Water Conservation Fund Act (LWCF) [16 U.S.C. 460(l)–8f].

4. *Wildlife*: Section 7 of the Endangered Species Act [16 U.S.C. 1536]; Migratory Bird Treaty Act [16 U.S.C. 703–712].

5. *Historic and Cultural Resources*: Section 106 of the National Historic Preservation Act of 1966, as amended [16 U.S.C. 470f].

6. *Social and Economic*: Title VI of the Civil Rights Act of 1964 [42 U.S.C. 2000(d) *et seq.*].

7. *Wetlands and Water Resources*: Clean Water Act [33 U.S.C. 1251–1377]; Rivers and Harbors Act of 1899 [33 U.S.C. 401–406]; Wild and Scenic Rivers Act [16 U.S.C. 1271–1287].

8. *Executive Orders*: Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations; E.O. 13175 Consultation and Coordination with Indian Tribal Governments.

(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.)

Authority: 23 U.S.C. 139(l)(1).

Issued On: October 16, 2009.

Michelle Eraut,

Environmental Program Manager, Salem, Oregon.

[FR Doc. E9–25419 Filed 10–21–09; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

October 16, 2009.

The Department of Treasury will submit the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13 on or after the date of publication of this notice. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 11000, 1750 Pennsylvania Avenue, NW., Washington, DC 20220.

DATES: Written comments should be received on or before November 23, 2009 to be assured of consideration.

Alcohol and Tobacco Tax and Trade Bureau (TTB)

OMB Number: 1513–0067.

Type of Review: Extension.

Title: Wholesale Dealers Applications, Letterheads, and Notices Relating to Operations. (Variations in Format or Preparation of Records) (TTB REC 5170/6)

Description: This information collection is used by permittees who wish to request a variance. We use written applications, letterheads, and notices to rule on proposed variations from standard requirements, to ascertain that revenue is not placed in jeopardy, and to protect the revenue.

Respondents: Businesses or other for-profits.

Estimated Total Burden Hours: 515 hours.

OMB Number: 1513–0104.

Type of Review: Extension.

Title: Information Collected in Support of Small Producer's Wine Tax Credit (TTB REC 5120/11)

Description: TTB collects this information to ensure proper tax credit. The information is used by taxpayers in preparing their returns and by TTB to verify tax computation. Recordkeepers are wine producers who want to transfer

their credit to warehouse operators and the transferees who take such credit.

Respondents: Businesses or other for-profits.

Estimated Total Burden Hours: 2,800 hours.

OMB Number: 1513–0014.

Type of Review: Extension.

Form: TTB F 5000.8.

Title: Power of Attorney.

Description: TTB F 5000.8 delegates the authority to a specific individual to sign documents on behalf of an applicant or principal. 26 U.S.C. 6061 authorizes that individuals signing returns, statements, or other documents required to be filed by industry members under the provisions of the IRC or the FAA Act, are to have that authority on file with TTB.

Respondents: Businesses or other for-profits.

Estimated Total Burden Hours: 3,333 hours.

OMB Number: 1513–0063.

Type of Review: Extension.

Title: Stills: Notices, Registration, and Records (TTB REC 5150/8)

Description: The information collection is used to account for and regulate the distillation of distilled spirits to protect the revenue and to provide for identification of distillers.

Respondents: Businesses or other for-profits.

Estimated Total Burden Hours: 42 hours.

OMB Number: 1513–0097.

Type of Review: Extension.

Title: Notices Relating to Payment of Firearms and Ammunition Excise Tax.

Description: Excise taxes are collected on the sale or use of firearms and ammunition by firearms or ammunition manufacturers, importers, or producers. Taxpayers who elect to pay excise taxes by electronic fund transfer must furnish a written notice upon election and discontinuance. Tax revenue will be protected.

Respondents: Businesses or other for-profits.

Estimated Total Burden Hours: 1 hour.

OMB Number: 1513–0009.

Type of Review: Extension.

Form: TTB F 5120.36, TTB F 5120.25.

Title: Application to Establish and Operate Wine Premises, and Wine Bond.

Description: TTB F 5120.25, Application to Establish and Operate Wine Premises, is the form used to establish the qualifications of an applicant applying to establish and operate wine premises. The applicant certifies his/her intention to produce and/or store a specified amount of wine

and take certain precautions to protect it from unauthorized use. TTB F 5120.36, Wine Bond, is the form used by the proprietor and a surety company as a contract to ensure the payment of the wine excise tax.

Respondents: Businesses or other for-profits.

Estimated Total Burden Hours: 2,150 hours.

OMB Number: 1513-0060.

Type of Review: Extension.

Title: Letterhead Applications and Notices Relating to Tax-Free Alcohol (TTB REC 5150/4)

Description: Tax-free alcohol is used for nonbeverage purposes in scientific research and medicinal uses by educational organizations, hospitals, laboratories, etc. Use of tax-free alcohol is regulated to prevent illegal diversion to taxable beverage use. Permits/Applications control authorized uses and flow. TTB REC 5150/4 is designed to protect revenue and public safety.

Respondents: Businesses or other for-profits.

Estimated Total Burden Hours: 2,222 hours.

OMB Number: 1513-0066.

Type of Review: Extension.

Title: Retail Liquor Dealers Records of Receipts of Alcoholic Beverages and Commercial Invoices (TTB REC 5170/3)

Description: The primary objectives of this recordkeeping requirement are revenue protection, by establishment of accountability data available for audit purposes and consumer protection, by subject record traceability of alcoholic beverages to the retail liquor dealer level of distribution in the event of defective products. This collection of information is contained in 27 CFR 31.234.

Respondents: Businesses or other for-profits.

Estimated Total Burden Hours: 1 hour.

Clearance Officer: Frank Foote, (202) 927-9347, Alcohol and Tobacco Tax and Trade Bureau, Room 200 East, 1310 G. Street, NW., Washington, DC 20005.

OMB Reviewer: Shagufta Ahmed, (202) 395-7873, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

Celina Elphage,

Treasury PRA Clearance Officer.

[FR Doc. E9-25472 Filed 10-21-09; 8:45 am]

BILLING CODE 4810-31-P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Additional Designation of one Individual Pursuant to Executive Order 13224

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The Treasury Department's Office of Foreign Assets Control ("OFAC") is publishing the name of one newly-designated individual whose property and interests in property are blocked pursuant to Executive Order 13224 of September 23, 2001, "Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten To Commit, or Support Terrorism."

DATES: The designation by the Director of OFAC of the individual identified in this notice, pursuant to Executive Order 13224, is effective on October 15, 2009.

FOR FURTHER INFORMATION CONTACT: Assistant Director, Compliance Outreach & Implementation, Office of Foreign Assets Control, Department of the Treasury, Washington, DC 20220, tel.: 202/622-2490.

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

This document and additional information concerning OFAC are available from OFAC's Web site (<http://www.treas.gov/ofac>) or via facsimile through a 24-hour fax-on-demand service, tel.: 202/622-0077.

Background

On September 23, 2001, the President issued Executive Order 13224 (the "Order") pursuant to the International Emergency Economic Powers Act, 50 U.S.C. 1701-1706, and the United Nations Participation Act of 1945, 22 U.S.C. 287c. In the Order, the President declared a national emergency to address grave acts of terrorism and threats of terrorism committed by foreign terrorists, including the September 11, 2001, terrorist attacks in New York, Pennsylvania, and at the Pentagon. The Order imposes economic sanctions on persons who have committed, pose a significant risk of committing, or support acts of terrorism. The President identified in the Annex to the Order, as amended by Executive Order 13268 of July 2, 2002, 13 individuals and 16 entities as subject to the economic sanctions. The Order was further amended by Executive Order 13284 of January 23, 2003, to reflect the creation of the Department of Homeland Security.

Section 1 of the Order blocks, with certain exceptions, all property and interests in property that are in or hereafter come within the United States or the possession or control of United States persons, of: (1) Foreign persons listed in the Annex to the Order; (2) foreign persons determined by the Secretary of State, in consultation with the Secretary of the Treasury, the Secretary of the Department of Homeland Security and the Attorney General, to have committed, or to pose a significant risk of committing, acts of terrorism that threaten the security of U.S. nationals or the national security, foreign policy, or economy of the United States; (3) persons determined by the Director of OFAC, in consultation with the Departments of State, Homeland Security and Justice, to be owned or controlled by, or to act for or on behalf of those persons listed in the Annex to the Order or those persons determined to be subject to subsection 1(b), 1(c), or 1(d)(i) of the Order; and (4) except as provided in section 5 of the Order and after such consultation, if any, with foreign authorities as the Secretary of State, in consultation with the Secretary of the Treasury, the Secretary of the Department of Homeland Security and the Attorney General, deems appropriate in the exercise of his discretion, persons determined by the Director of OFAC, in consultation with the Departments of State, Homeland Security and Justice, to assist in, sponsor, or provide financial, material, or technological support for, or financial or other services to or in support of, such acts of terrorism or those persons listed in the Annex to the Order or determined to be subject to the Order or to be otherwise associated with those persons listed in the Annex to the Order or those persons determined to be subject to subsection 1(b), 1(c), or 1(d)(i) of the Order.

On October 15, 2009, the Director of OFAC, in consultation with the Departments of State, Homeland Security, Justice and other relevant agencies, designated, pursuant to one or more of the criteria set forth in subsections 1(b), 1(c) or 1(d) of the Order, one individual whose property and interests in property are blocked pursuant to Executive Order 13224.

The designee is as follows:
HARRACH, Bekkay (a.k.a. AL HAFIDH ABU TALHA DER DEUTSCHE); DOB 4 Sep 1977; POB Berkane, Morocco; nationality Germany; Driver's License No. J17001W6Z12; National ID No. 5209243072 (Germany) expires 7 Sep 2013; Passport 5208116575 (Germany) expires 7 Sep 2013; Believed to be in the Afghanistan/

Pakistan border area (individual) [SDGT].

Dated: October 15, 2009.

Adam J. Szubin,

Director, Office of Foreign Assets Control.

[FR Doc. E9-25415 Filed 10-21-09; 8:45 am]

BILLING CODE 4811-45-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

[FI-59-91]

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning an existing final regulation, FI-59-91 (TD 8674), Debt Instructions With Original Issue Discount; Contingent Payment; Anti-Abuse Rule (§§ 1.1275-2, 1.1275-3, 1.1275-4, and 1.275-6).

DATES: Written comments should be received on or before December 21, 2009 to be assured of consideration.

ADDRESSES: Direct all written comments to R. Joseph Durbala, Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulation should be directed to Allan Hopkins, at (202) 622-6665, or at Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or through the Internet, at Allan.M.Hopkins@irs.gov.

SUPPLEMENTARY INFORMATION:

Title: Debt Instruments With Original Issue Discount; Contingent Payments; Anti-Abuse Rule.

OMB Number: 1545-1450.

Regulation Project Number: FI-59-91.

Abstract: This regulation relates to the tax treatment of debt instruments that provide for one or more contingent payments. The regulation also treats a debt instrument and a related hedge as an integrated transaction. The regulation

provides general rules, definitions, and reporting and recordkeeping requirements for contingent payment debt instruments and for integrated debt instruments.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, individuals, and state, local, or tribal governments.

Estimated Number of Respondents: 180,000.

Estimated Time per Respondent: 30 minutes.

Estimated Total Annual Burden Hours: 89,000.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. 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 tax return information are confidential, as required by 26 U.S.C. 6103.

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. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: October 9, 2009.

R. Joseph Durbala,

IRS Reports Clearance Officer.

[FR Doc. E9-25381 Filed 10-21-09; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

[REG-246249-96]

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning an existing final regulation, REG-246249-96 (TD 9010), Information Reporting Requirements for Certain Payments Made on Behalf of Another Person, Payments to Joint Payees, and Payments of Gross Proceeds From Sales Involving Investment Advisers (§§ 1.6041-1 and 1.6045-1).

DATES: Written comments should be received on or before December 21, 2009 to be assured of consideration.

ADDRESSES: Direct all written comments to R. Joseph Durbala, Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulations should be directed to Allan Hopkins, at Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or at (202) 622-6665, or through the Internet at Allan.M.Hopkins@irs.gov.

SUPPLEMENTARY INFORMATION:

Title: Information Reporting Requirements for Certain Payments Made on Behalf of Another Person, Payments to Joint Payees, and Payments of Gross Proceeds From Sales Involving Investment Advisers.

OMB Number: 1545-1705.

Regulation Project Number: REG-246249-96.

Abstract: This regulation under section 6041 clarifies who is the payee for information reporting purposes if a check or other instrument is made payable to joint payees, provides information reporting requirements for escrow agents and other persons making payments on behalf of another person, and clarifies that the amount to be

reported as paid is the gross amount of the payment. The regulation also removes investment advisers from the list of exempt recipients for information reporting purposes under section 6045.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

The estimate of the reporting burden in § 1.6041-1 is reflected in the burden of Form 1099-MISC. The estimate of the reporting burden in § 1.6045-1 is reflected in the burden of Form 1099-B.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. 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 tax return information are confidential, as required by 26 U.S.C. 6103.

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. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: October 13, 2009.

R. Joseph Durbala,

IRS Reports Clearance Officer.

[FR Doc. E9-25382 Filed 10-21-09; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

[CO-93-90]

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning an existing final regulation, CO-93-90 (TD 8364), Corporations; Consolidated Returns-Special Rules Relating To Dispositions and Deconsolidations of Subsidiary Stock (§§ 1.337(d)-2 and 1.1502-20).

DATES: Written comments should be received on or before December 21, 2009 to be assured of consideration.

ADDRESSES: Direct all written comments to R. Joseph Durbala, Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulations should be directed to Allan Hopkins at Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or at (202) 622-6665, or through the Internet at Allan.M.Hopkins@irs.gov.

SUPPLEMENTARY INFORMATION:

Title: Corporations; Consolidated Returns-Special Rules Relating To Dispositions and Deconsolidations of Subsidiary Stock.

OMB Number: 1545-1160.

Regulation Project Number: CO-93-90.

Abstract: This regulation prevents elimination of corporate-level tax because of the operation of the consolidated returns investment adjustment rules. Statements are required for dispositions of a subsidiary's stock for which losses are claimed, for basis reductions within 2 years of the stock's deconsolidation, and for elections by the common parent to retain the net operating losses of a disposed subsidiary.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 3,000.

Estimated Time per Respondent: 2 hours.

Estimated Total Annual Burden Hours: 6,000.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. 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 tax return information are confidential, as required by 26 U.S.C. 6103.

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. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: October 9, 2009.

R. Joseph Durbala,

IRS Reports Clearance Officer.

[FR Doc. E9-25383 Filed 10-21-09; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

[REG-209373-81]

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning an existing final regulation, REG-209373-81 (TD 8797), Election to Amortize Start-Up Expenditures for Active Trade or Business (§ 1.195-1).

DATES: Written comments should be received on or before December 21, 2009 to be assured of consideration.

ADDRESSES: Direct all written comments to R. Joseph Durbala, Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulation should be directed to Allan Hopkins, at (202) 622-6665, or at Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or through the Internet, at Allan.M.Hopkins@irs.gov.

SUPPLEMENTARY INFORMATION:

Title: Election to Amortize Start-Up Expenditures for Active Trade or Business.

OMB Number: 1545-1582.

Regulation Project Number: REG-209373-81.

Abstract: Section 1.195-1 of the regulation provides that start-up expenditures may, at the discretion of the taxpayer, be amortized over a period of not less than 60 months beginning with the month the active trade or business begins. Taxpayers may elect to amortize start-up expenditures by filing a statement with their tax return for the taxable year in which the trade or business begins.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 150,000.

Estimated Time per Respondent: 15 minutes.

Estimated Total Annual Burden Hours: 37,500.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information

unless the collection of information displays a valid OMB control number. 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 tax return information are confidential, as required by 26 U.S.C. 6103.

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. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: October 13, 2009.

R. Joseph Durbala,

IRS Reports Clearance Officer.

[FR Doc. E9-25280 Filed 10-21-09; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 6118

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 6118, Claim of Income Tax Return Preparer Penalties.

DATES: Written comments should be received on or before December 21, 2009 to be assured of consideration.

ADDRESSES: Direct all written comments to R. Joseph Durbala, Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Allan Hopkins at Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or at (202) 622-6665, or through the Internet at Allan.M.Hopkins@irs.gov.

SUPPLEMENTARY INFORMATION:

Title: Claim of Income Tax Return Preparer Penalties.

OMB Number: 1545-0240.

Form Number: 6118.

Abstract: Form 6118 is used by tax return preparers to file for a refund of penalties incorrectly charged. The information enables the IRS to process the claim and have the refund issued to the tax return preparer.

Current Actions: Although there were no significant changes being made to the form at this time, we recalculated the burden to more accurately reflect the structure of the form.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations and individuals or households.

Estimated Number of Respondents: 10,000.

Estimated Time per Respondent: 1 hour, 8 minutes.

Estimated Total Annual Burden Hours: 11,400.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. 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 tax return information are confidential, as required by 26 U.S.C. 6103.

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.

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the

collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: October 9, 2009.

R. Joseph Durbala,

IRS Reports Clearance Officer.

[FR Doc. E9-25384 Filed 10-21-09; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF THE TREASURY

Comptroller of the Currency

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995. An agency may not conduct or sponsor, and a respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. The OCC is soliciting comment concerning its information collection titled, "Risk-Based Capital Standards—Advanced Capital Adequacy Framework." The OCC also gives notice that it has sent the information collection to OMB for review.

DATES: Comments must be submitted on or before November 23, 2009.

ADDRESSES: You should direct your comments to: Communications Division, Office of the Comptroller of the Currency, Public Information Room, Mail Stop 2-3, Attention: 1557-0234, 250 E Street, SW., Washington, DC 20219. In addition, comments may be sent by fax to (202) 874-5274, or by electronic mail to regs.comments@occ.treas.gov. You may personally inspect and photocopy comments at the OCC, 250 E Street, SW., Washington, DC. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling

(202) 874-4700. Upon arrival, visitors will be required to present valid government-issued photo identification and submit to security screening in order to inspect and photocopy comments.

Additionally, you should send a copy of your comments to: OCC Desk Officer [1557-0234], by mail to the Office of Information and Regulatory Affairs, U.S. Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street, NW., Washington, DC 20503, or by fax to (202) 395-6974.

FOR FURTHER INFORMATION CONTACT: You can request additional information or a copy of the collection from Mary H. Gottlieb, OCC Clearance Officer, (202) 874-5090, Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, 250 E Street, SW., Washington, DC 20219.

SUPPLEMENTARY INFORMATION: The OCC is proposing to extend without change approval of the following information collection:

Title: Risk-Based Capital Standards—Advanced Capital Adequacy Framework.

OMB Control No.: 1557-0234.

Frequency of Response: Annually and quarterly.

Affected Public: National banks and Federal branches and agencies of foreign banks.

Number of Respondents: 52.

Number of Responses per

Respondent: 24.

Total Number of Responses: 1,248.

Burden per Respondent: 15,570 hours.

Total Estimated Annual Burden:

809,640 hours.

General Description of Report: This information collection is mandatory: 12 U.S.C. 93a, 161, 3907-3909. The written implementation plan and prior approvals are given confidential treatment: 5 U.S.C. 552 (b)(8).

Abstract: On December 7, 2007, the Federal banking agencies¹ issued a joint final rule titled Risk-Based Capital Standards: Advanced Capital Adequacy Framework (final rule) implementing a new risk-based regulatory capital framework for institutions in the United States.² The final rule requires certain large or internationally active banks and bank holding companies to: (1) Adopt a written implementation plan; (2) update that plan for any mergers; (3) obtain prior written approvals for the use of certain approaches for determining risk-weighted assets; and (4) make certain public disclosures regarding their

¹ Board of Governors of the Federal Reserve System; Federal Deposit Insurance Corporation; and Office of Thrift Supervision.

² 72 FR 69288 (December 7, 2007).

capital ratios, their components, and information on implicit support provided to a securitization. The required reporting forms have been approved under OMB Control No. 1557-0239.

Request for Comment

The Federal banking agencies issued a 60-day notice for comment on July 17, 2009. 74 FR 34865. No comments were received. Comments continue to be invited on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility;

(b) The accuracy of the agency's estimate of the burden of the collection of information;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: October 15, 2009.

Michele Meyer,

Assistant Director, Legislative and Regulatory Activities Division.

[FR Doc. E9-25327 Filed 10-21-09; 8:45 am]

BILLING CODE 4810-33-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

[REG-109481-99]

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning an existing final regulation, REG-109481-99 (TD 9076), Special Rules Under Section 417(a)(7) for Written

Explanation Provided by Qualified Retirement Plan After Annuity Starting Dates (§ 1.417(e)-1).

DATES: Written comments should be received on or before December 21, 2009 to be assured of consideration.

ADDRESSES: Direct all written comments to R. Joseph Durbala, Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulations should be directed to Allan Hopkins at Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or at (202) 622-6665, or through the Internet at Allan.M.Hopkins@irs.gov.

SUPPLEMENTARY INFORMATION:

Title: Special Rules Under Section 417(a)(7) for Written Explanation Provided by Qualified Retirement Plan After Annuity Starting Dates.

OMB Number: 1545-1724.

Regulation Project Number: REG-109481-99.

Abstract: The collection of information requirement in section 1.417(e)-1(b)(3)(iv)(B) and 1.417(e)-1(b)(3)(v)(A) is required to ensure that a participant and the participant's spouse consent to a form of distribution from a qualified plan that may result in reduced periodic payments.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of currently approved collection.

Affected Public: Individuals or households, business or other for-profit organizations, and not-for-profit institutions.

Estimated Number of Respondents: 50,000.

Estimated Time per Respondent: 15 minutes.

Estimated Total Annual Burden Hours: 12,500.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. 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 tax return information are confidential, as required by 26 U.S.C. 6103.

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. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: October 13, 2009.

R. Joseph Durbala,

IRS Reports Clearance Officer.

[FR Doc. E9-25385 Filed 10-21-09; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

[REG-105946-00]

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning an existing final regulation, REG-105946-00 (TD 8995), Mid-Contract Change in Taxpayer (§ 1.460-6).

DATES: Written comments should be received on or before December 21, 2009 to be assured of consideration.

ADDRESSES: Direct all written comments to R. Joseph Durbala, Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of regulations should be directed to Allan Hopkins at Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224,

or at (202) 622-6665, or through the Internet at Allan.M.Hopkins@irs.gov.

SUPPLEMENTARY INFORMATION:

Title: Mid-Contract Change in Taxpayer.

OMB Number: 1545-1732.

Regulation Project Number: REG-105946-00.

Abstract: The information is needed by taxpayers who assume the obligation to account for the income from long-term contracts as the result of certain nontaxable transactions.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 5,000.

Estimated Time per Respondent: 2 hours.

Estimated Total Annual Burden Hours: 10,000.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. 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 tax return information are confidential, as required by 26 U.S.C. 6103.

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. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: October 13, 2009.

R. Joseph Durbala,

IRS Reports Clearance Officer.

[FR Doc. E9-25386 Filed 10-21-09; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 706-GS(D)

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 706-GS(D), Generation-Skipping Transfer Tax Return for Distributions.

DATES: Written comments should be received on or before December 21, 2009 to be assured of consideration.

ADDRESSES: Direct all written comments to R. Joseph Durbala, Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Allan Hopkins, at (202) 622-6665, or at Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or through the Internet, at Allan.M.Hopkins@irs.gov.

SUPPLEMENTARY INFORMATION:

Title: Generation-Skipping Transfer Tax Return for Distributions.

OMB Number: 1545-1144.

Form Number: 706-GS(D).

Abstract: Form 706-GS(D) is used by persons who receive taxable distributions from a trust to compute and report the generation-skipping transfer tax imposed by Internal Revenue Code section 2601. IRS uses the information to verify that the tax has been properly computed.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households.

Estimated Number of Respondents: 1,000.

Estimated Time per Respondent: 59 minutes.

Estimated Total Annual Burden Hours: 980.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. 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 tax return information are confidential, as required by 26 U.S.C. 6103.

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. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: October 13, 2009.

R. Joseph Durbala,

IRS Reports Clearance Officer.

[FR Doc. E9-25387 Filed 10-21-09; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF THE TREASURY

Fiscal Service

Surety Companies Acceptable on Federal Bonds-Terminations: Excelsior Insurance Company; Peerless Indemnity Insurance Company; Consolidated Insurance Company; Indiana Insurance Company; The Netherlands Insurance Company; The Midwestern Indemnity Company

AGENCY: Financial Management Service, Fiscal Service, Department of the Treasury.

ACTION: Notice.

SUMMARY: This is Supplement No. 3 to the Treasury Department Circular 570, 2009 Revision, published July 1, 2009, at 74 FR 31536.

FOR FURTHER INFORMATION CONTACT: Surety Bond Branch at (202) 874-6850.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the Certificates of Authority issued by the Treasury to the above-named companies under 31 U.S.C. 9305 to qualify as acceptable sureties on Federal bonds were terminated effective October 8, 2009. Federal bond-approving officials should annotate their reference copies of the Treasury Department Circular 570 ("Circular"), 2009 Revision, to reflect this change.

With respect to any bonds currently in force with these companies, bond approving officers may let such bonds run to expiration and need not secure new bonds. However, no new bonds should be accepted from these companies, and bonds that are continuous in nature should not be renewed.

The Circular may be viewed and downloaded through the Internet at <http://www.fms.treas.gov/c570>.

Questions concerning this notice may be directed to the U.S. Department of the Treasury, Financial Management Service, Financial Accounting and Services Division, Surety Bond Branch, 3700 East-West Highway, Room 6F01, Hyattsville, MD 20782.

Dated: October 9, 2009.

Laura Carrico,

Acting Director, Financial Accounting and Services Division.

[FR Doc. E9-25298 Filed 10-21-09; 8:45 am]

BILLING CODE 4810-35-M



Federal Register

**Thursday,
October 22, 2009**

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

**42 CFR Parts 417, 422, 423 et al.
Medicare Program; Policy and Technical
Changes to the Medicare Advantage and
the Medicare Prescription Drug Benefit
Programs; Proposed Rule**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 417, 422, 423, and 480

[CMS-4085-P]

RIN 0938-AP77

Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: We are proposing revisions to the Medicare Advantage (MA) program (Part C) and prescription drug benefit program (Part D) based on our continued experience in the administration of the Part C and D programs. The proposed revisions clarify various program participation requirements; specify changes to strengthen beneficiary protections; ensure that plan offerings to beneficiaries include meaningful differences; improve plan payment rules and processes; and implement new policy such as a Part D formulary policy.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. Eastern Standard Time (EST) on December 8, 2009.

ADDRESSES: In commenting, please refer to file code CMS-4085-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-4085-P, P.O. Box 8013, Baltimore, MD 21244-8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human

Services, *Attention:* CMS-4085-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses: a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-7195 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.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the "Collection of Information Requirements" section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Alissa Deboy, (410) 786-6041, General information and Part D issues.

Sabrina Ahmed, (410) 786-7499, Part C issues.

Chris Eisenberg, (410) 786-5509, Risk adjustment data validation issues.

Terry Lied, (410) 786-8973, Collection of information requirements and regulatory impact analysis issues.

Kristy Nishimoto, (410) 786-8517, Part C and D enrollment and appeals issues.

Christine Reinhard, (410) 786-2987, Part C and D compliance and sanction issues.

Frank Szefflinski, (303) 844-7119, Part C payment issues.

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.

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- F. Changes To Implement New Policy
 1. Protected Classes of Concern Under Part D (§ 423.120(b)(2)(v))
2. Pro-rating the Plan Deductible for Part C MSA Enrollments Occurring During an Initial Coverage Election Period (§ 422.103)
- G. Changes To Clarify Various Program Participation Requirements
 1. Uniform Benefits Under Parts C and D (§ 422.100(d) and § 423.104))
 2. Ensuring the Security of Personal Health Information and Other Personally Identifiable Information (§ 422.504 and § 423.505)
 3. Requirement for Sponsoring Organizations Under Parts C and D To Report Other Payer Information to the Coordination of Benefits Contractor (§ 422.108 and § 423.464)
 4. Visitor/Traveler Benefit Under Part C for the Purpose of Extending Enrollment Up to 12 Months (§ 422.74)
 5. Medication Therapy Management Programs Under Part D (§ 423.153(d))
 6. Formulary Requirements-Development and Revision by a Pharmacy and Therapeutics Committee (§ 423.120)
 7. Generic Equivalent Disclosure Under Part D (§ 423.132)
 8. Access to Covered Part D Drugs (§ 423.120)
 9. Standard Timeframe and Notice Requirements for Coverage Determinations Under Part D (§ 423.568)
 10. Expediting Certain Coverage Determinations (§ 423.570)
 11. Timeframes and Notice Requirements for Expedited Coverage Determinations (§ 423.572)
 12. Clarify Novation Agreements Under Part D (§ 423.551)
 13. Cost Contract Program Revisions: Appeals and Marketing Requirements (§ 417.428, § 417.494, § 417.500, and § 417.640)
 14. Appeals Processes for Contract Determinations, Intermediate Sanctions, and Civil Money Penalties
 - a. Contract Determinations (§ 417.492 and 417.494)
 - b. Civil Money Penalties (§ 417.500)
 - c. Intermediate Sanctions (§ 417.500)
 15. Extending MA Marketing Requirements to Cost Program Plans (§ 417.428)
 - a. Definitions Concerning Marketing Materials (§ 422.2260)
 - b. Review and Distribution of Marketing Materials (§ 422.2262)
 - c. Guidelines for CMS Review (§ 422.2264)
 - d. Deemed Approval (§ 422.2266)
 - e. Standards for MA Organization Marketing (§ 422.2268)
 - f. Licensing of Marketing Representatives and Confirmation of Marketing Resources (§ 422.2272)
 - g. Broker and Agent Requirements (§ 422.2274)
- H. Changes To Implement Corrections and Other Technical Changes
 1. Application of Subpart M to Health Care Prepayment Plans (§ 417.840)
 2. Generic Notice Delivery Requirements (§ 422.622 and 422.626)
 3. Revision to Definition of Gross Covered Prescription Drug Costs (§ 423.308)
 4. Application Evaluation Procedures (§ 422.502(c and d) and § 423.503(c and d))

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- F. ICRs Regarding RADV Audit Dispute and Appeal Processes (§ 422.311)
- G. ICRs Regarding Application Requirements (§ 422.501 and § 423.502)
- H. ICRs Regarding General Provisions (§ 422.503 and § 423.504)
- I. ICRs Regarding Contract Provisions (§ 422.504 and 423.505)
- J. ICRs Regarding Nonrenewal of Contract (§ 422.506 and § 423.507)
- K. ICRs Regarding Request for Hearing (§ 422.662 and § 423.651)
- L. ICRs Regarding Time and Place of Hearing (§ 422.670 and § 423.655)
- M. ICRs Regarding Review by the Administrator (§ 422.692 and § 423.666)
- N. ICRs Regarding Procedures for Imposing Intermediate Sanctions and Civil Monetary Penalties (§ 422.756 and § 423.756)
- O. ICRs Regarding Disclosure of Part D Plan Information (§ 423.128)
- P. ICRs Regarding Consumer Satisfaction Surveys (§ 423.156)
- Q. ICRs Regarding Validation of Part C and Part D Reporting Requirements (§ 422.516 and § 423.514)
- R. ICRs Regarding Drug Utilization Management, Quality Assurance, and Medication Therapy Management Programs (MTMPs) (§ 423.153)
- S. ICRs Regarding Timeframes and Notice Requirements for Standard Coverage Determinations (§ 423.568)
- T. ICRs Regarding Timeframes and Notice Requirements for Expedited Coverage Determinations (§ 423.572)
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- A. Overall Impact
- B. Increase in Costs to MA Organizations and Part D Sponsors
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- c. Clarify That CMS May Require a "Test Period" During an Enrollment/Marketing Sanction
- d. Right for CMS To Require an Independent Audit of Sponsoring Organizations Under Intermediate Sanction
- e. The Ability for CMS To Require Sponsors To Disclose to Current and Potential Enrollees Compliance and Performance Deficiencies
- f. Section 176 of MIPPA—Formulary and Protected Classes Requirements (Part D)
- g. Reducing Duplicative and Low Enrollment Plans (Parts C & D)
- h. Validation of Part C and Part D Reporting Requirements
- F. Accounting Statement
- G. Conclusion
- Regulations Text
- Acronyms**
- AO Accrediting Organization
- ADS Automatic Dispensing System
- AEP Annual Enrollment Period
- AHFS—DI American Hospital Formulary Service
- AHFS—DI American Hospital Formulary Service—Drug Information
- AHRQ Agency for Health Care Research and Quality
- ALJ Administrative Law Judge
- BBA Balanced Budget Act of 1997 (Pub. L. 105–33)
- BBRA [Medicare, Medicaid and State Child Health Insurance Program] Balanced Budget Refinement Act of 1999 (Pub. L. 106–113)
- BIPA Medicare, Medicaid, and SCHIP Benefits Improvement Protection Act of 2000 (Pub. L. 106–554)
- CAHPS Consumer Assessment Health Providers Survey
- CAP Corrective Action Plan
- CCIP Chronic Care Improvement Program
- CMR Comprehensive Medical Review
- CMP Civil Money Penalties
- CMR Comprehensive Medical Review
- CMS Centers for Medicare & Medicaid Services
- CMS—HCC CMS Hierarchal Condition Category
- CTM Complaints Tracking Module
- COB Coordination of Benefits
- CORF Comprehensive Outpatient Rehabilitation Facility
- CY Calendar year
- DOL U.S. Department of Labor
- DRA Deficit Reduction Act of 2005 (Pub. L. 109–171)
- EGWP Employer Group/Union-Sponsored Waiver Plan
- EOB Explanation of Benefits
- ESRD End-stage renal disease
- FACA Federal Advisory Committee Act
- FDA Food and Drug Administration (HHS)
- FEHBP Federal Employees Health Benefits Plan
- FFS Fee-For-Service
- FY Fiscal year
- GAO Government Accountability Office
- HCPP Health Care Prepayment Plans
- HEDIS HealthCare Effectiveness Data and Information Set
- HHS [U.S. Department of] Health and Human Services
- HIPAA Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191)
- HMO Health Maintenance Organization
- HOS Health Outcome Survey
- HPMS Health Plan Management System
- ICD–9–CM Internal Classification of Disease, 9th, Clinical Modification Guidelines
- ICEP Initial Coverage Enrollment Period
- ICL Initial Coverage Limit
- ICR Information Collection Requirement
- LEP Late Enrollment Penalty
- LIS Low Income Subsidy
- LTC Long Term Care
- LTCF Long Term Care Facility
- MA Medicare Advantage
- MAAA American Academy of Actuaries
- MAO Medicare Advantage Operations
- MA–PD Medicare Advantage-Prescription Drug Plans
- M+C Medicare+Choice program
- MPDPF Medicare Prescription Drug Plan Finder
- MIPPA Medicare Improvements for Patients and Providers Act of 2008
- MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173)
- MSA Metropolitan Statistical Area
- MSAs Medical Savings Accounts
- MSP Medicare Secondary Payer
- MTM Medication Therapy Management
- MTMP Medication Therapy Management Programs
- NAIC National Association Insurance Commissioners
- NCPDP National Council for Prescription Drug Programs
- NGC National Guideline Clearinghouse
- NIH National Institutes of Health
- NOMNC Notice of Medicare Non-coverage
- OEP Open Enrollment Period
- OIG Office of Inspector General
- OMB Office of Management and Budget
- OPM Office of Personnel Management
- OTC Over the Counter
- PART C Medicare Advantage
- PART D Medicare Prescription Drug Benefit Programs
- PBM Pharmacy Benefit Manager
- PDE Prescription Drug Event
- PDP Prescription drug plan
- PFFS Private Fee For Service Plan
- POS Point of Service
- PPO Preferred Provider Organization
- PPS Prospective Payment System
- P&T Pharmacy & Therapeutics
- QIO Quality Improvement Organization
- QRS Quality Review Study
- PACE Programs of All Inclusive Care for the Elderly
- RAPS Risk Adjustment Payment System
- RADV Risk Adjustment Data Validation
- SCHIP State Children's Health Insurance Programs

SEP Special Enrollment Periods
 SHIP State Health Insurance Assistance Programs
 SNF Skilled Nursing Facility
 SNP Special Needs Plan
 SPAP State Pharmaceutical Assistance Programs
 SSI Supplemental Security Income
 TrOOP True Out Of Pocket
 U&C Usual and Customary
 USP U.S. Pharmacopoeia

I. Background

A. Overview of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) was enacted on December 8, 2003. The MMA established the Part D program and made revisions to the provisions in Part C of the Medicare statute governing the Medicare Advantage (MA) program. The MMA directed that important aspects of the new Medicare prescription drug benefit program under Part D be similar to and coordinated with regulations for the MA program.

The MMA also directed implementation of the prescription drug benefit and revised MA program provisions effective January 1, 2006. The final rules for the MA and Part D prescription drug programs appeared in the **Federal Register** on January 28, 2005 (70 FR 4588–4741 and 70 FR 4194–4585, respectively). Many of the provisions relating to applications, marketing, contracts, and the new bidding process for the MA program became effective on March 22, 2005, 60 days after publication of the rule, so that the requirements for both programs could be implemented by January 1, 2006. All of the provisions regarding the new Part D prescription drug program became effective on March 22, 2005.

As we have gained more experience with the MA program and the prescription drug benefit program, we have revised the Part C and D regulations to continue to improve or clarify existing policies and/or codify current guidance for both programs. For example, in December 2007, we published a final rule with comment on contract determinations involving Medicare Advantage (MA) organizations and Medicare Part D prescription drug plan sponsors (72 FR 68700). In April 2008, we published a final rule to address policy and technical changes to the Part D program (73 FR 20486). In September 2008 and January 2009, we finalized revisions to both the Medicare Advantage and prescription drug benefit programs (73 FR 54226 and 74 FR 1494, respectively) to implement provisions in

the Medicare Improvement for Patients and Providers Act (MIPPA) (Pub. L. 110–275), which contained provisions impacting both the Medicare Part C and D programs, and make other policy clarifications based on experience with both programs (73 FR 54208, 73 FR 54226, and 74 FR 2881).

Under this proposed rule, we have identified additional programmatic and operational changes (outlined below) that we believe are needed in order to further improve our oversight and management of the Part C and D programs and to further improve beneficiary experience under MA or Part D plans.

B. History and Overview

The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) established a new “Part C” in the Medicare statute (sections 1851 through 1859 of the Social Security Act (the Act)) which provided for what was then called the Medicare+Choice (M+C) program. Under section 1851(a)(1) of the Act, every individual entitled to Medicare Part A and enrolled under Medicare Part B, except for most individuals with end-stage renal disease (ESRD), could elect to receive benefits either through the original Medicare program or an M+C plan, if one was offered where he or she lived. The primary goal of the M+C program was to provide Medicare beneficiaries with a wider range of health plan choices. The M+C provisions in Part C were amended by the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–111), and further amended by the Medicare, Medicaid, and State Children’s Health Insurance Program (SCHIP) Benefits Improvement Act of 2000 (BIPA) (Pub. L. 106–554).

As noted previously, the MMA was enacted on December 8, 2003. Title I of the MMA added a new “Part D” to the Medicare statute (sections 1860D–1 through 42 of the Act) creating the Medicare Prescription Drug Benefit Program, one of the most significant changes to the Medicare program since its inception in 1965. Sections 201 through 241 of Title II of the MMA made significant changes to the M+C program. Title II of the MMA renamed the M+C program as the MA program and included new payment and bidding provisions, new regional MA plans and special needs plans, reestablished authority for medical savings account (MSA) plans that had been provided in the BBA on a temporary basis, addressed private fee-for-service plans, and made other changes. Title I of the MMA created prescription drug benefits

under Medicare Part D, and a new retiree drug subsidy program.

Both the MA and prescription drug benefit regulations were published separately, as proposed and final rules, though their development and publication were closely coordinated. On August 3, 2004, we published in the **Federal Register** proposed rules for the MA program (69 FR 46866 through 46977) and the prescription drug benefit program (69 FR 46632 through 46863). In response to public comments on the proposed rules, we made several revisions to the proposed policies for both programs. For further discussion of these revisions, see the respective final rules (70 FR 4588 through 4741) and (70 FR 4194 through 4585).

Also as noted above, MIPPA was enacted on July 15, 2008, which addressed a number of provisions impacting the Part C and D programs, including provisions impacting marketing under both programs. In the September 18, 2008 **Federal Register** (73 FR 54208), we published a final rule that finalized certain marketing provisions, effective October 1, 2008, that paralleled provisions in MIPPA. In the same issue of the **Federal Register** (73 FR 54226), we published a separate interim final rule that addressed the other provisions of MIPPA affecting the MA and Part D programs. We also clarified the MIPPA marketing provisions in a November 2008 interim final rule (73 FR 67407 and issued a separate interim final rule in January 2009 to address MIPPA provisions related to Part D plan formularies (74 FR 2881).

Now, with almost four years’ experience behind us, we are proposing further revisions to these programs affecting both beneficiaries and sponsoring organizations.

When the MMA required that the Part D benefit afford each enrollee a minimum of two choices in each plan region, few if any envisioned the overwhelming response from the healthcare industry would result in most beneficiaries choosing among dozens of plans with various benefit packages. In the first few years of the Part D benefit, we believed this was on the whole a great success. More plans means more variation, competition and lower prices for Medicare beneficiaries choosing to enroll in a stand-alone prescription drug plan (PDP), or Medicare Advantage prescription drug plan (MA–PD). However, with so many plans to choose from many beneficiaries reportedly find the annual task of selecting one plan from so many overwhelming, and confusing. Moreover, we have found that, as

overseers of the Part C and D programs, organizations submitting bids to offer multiple plans have not consistently submitted plan benefit designs that were significantly different from each other, which can add to beneficiary confusion.

Since its inception in 2006, the Medicare Part D program has improved access to drug coverage for elderly and offered beneficiaries a wide range of plans from which to choose. At the same time, some have suggested that significant numbers of beneficiaries are confused by the array of choices and find it difficult to make enrollment decisions that are best for them. Many do not enroll in necessarily the lowest cost plan and many eligible individuals are not enrolled in the low-income subsidy program. Finally, once beneficiaries have chosen a plan and enrolled in it, they tend to remain in those plans, despite changes in medication use or premium increases.

We remain committed to considering changes in the way we administer the Part C and D programs to enable Medicare beneficiaries to choose the plan that best suits their needs. Among other proposals, we are making following three specific proposals to simplify the program for beneficiaries:

- First, we propose to require sponsors to ensure that when they provide multiple plan offerings, those offerings sufficiently differ and thereby provide beneficiaries meaningful options (*see* section II. of this proposed rule);
- Second, we propose to eliminate plans with persistently low enrollments, since these can add complexity to choices without adding value (*see* section II.D. of this proposed rule);
- Third, we propose to require sponsors to use standardized “templates” in their beneficiary communication materials (for example, the Annual Notice of Changes (ANOC) and the Evidence of Coverage (EOC) notices), so that seniors can better understand how their current benefits and cost-sharing requirements will be changing and more easily compare their current plan with other plan options (*see* section II.B.3 of this proposed rule).

We believe that more can be done to structure choices for seniors to aid them in making better plan choices.^{1 2} For example, studies have suggested that providing personalized drug utilization and cost information to beneficiaries

can encourage seniors to switch to plans that better meet their medication needs while reducing their overall costs.³ Some have urged that the agency can do more to provide improved individual drug utilization and cost information to beneficiaries to encourage seniors to switch to lower-cost plans. Other studies have found that some beneficiaries are not fully aware of the financial implications of deferring enrollment in drug plans,⁴ a finding that suggests that we could do more to make those implications more salient to beneficiaries. We invite comments on these possibilities and other improvements the agency can make, to help beneficiaries choose the plans that best suit their needs. We also invite comment on the type of research that might be undertaken to help inform future regulatory and programmatic improvements and how we can best support our partners, such as states, to assist them in helping beneficiaries enroll in the best possible plans. For example, we are interested in assessing the impacts of random auto-assignments on low-income beneficiaries. To the extent that States are interested in exploring non-random assignment methods, we invite comment on what type of information States would find most beneficial, including the types of data analyses we could potentially undertake with the data we already have from States who utilize non-random assignment methods.

We also have found that in certain cases, we have been limited by existing program rules and regulations to implement actions that would improve sponsoring organization performance. Toward this end, we propose provisions that would limit the number of plan offerings by eliminating duplicative bids, and strengthen our program participation requirements.

We are proposing a number of additional provisions aimed at strengthening existing beneficiary protections. For example, we propose to strengthen plan transition process requirements to ensure maximum transparency regarding our expectations of Part D plans with respect to enrollees transitioning to the plan from other drug

coverage and to ensure that current subregulatory practices are codified in regulation.

We are also proposing another set of provisions that are aimed at improving payment rules and processes, and improving data collection for oversight and quality assessment. For example, we are proposing to expand the collection of prescription drug event data that we currently collect for research and other non-payment related purposes. Collecting these additional data, which are currently collected for payment purposes, would provide us additional information to conduct analyses that may be used to improve policies and assist in monitoring of Part D plan sponsors.

In addition, we are proposing significant new Part D policy in this rule. For example, in the area of Part D formulary policy, we propose a regulatory interpretation of MIPPA protected drug categories and classes provision in section 176 of MIPPA (Pub. L. 110–275) that we previously addressed in a January 19, 2009 interim final rule with comment period (IFC). Based on comments received in response to that IFC, we believe that interpretation of statutory terms is needed. In addition, we believe that additional clarification is needed relative to the process that we intend to utilize to identify the protected categories and classes of drugs that must be listed on all Part D plan formularies.

Finally, we propose other provisions that are aimed at further clarifying existing policy and we make technical corrections where needed. For example, in some cases, we are addressing topic areas that were included in our 2010 call letter to Part C and D plans, the document that outlines policy clarifications and reminders for plans bidding on plan offerings in the coming contract cycle. In the spirit of transparency, we have outlined some of these clarifications within this rule so to ensure the public has a full opportunity to comment on our policies.

II. Provisions of the Proposed Regulations

In the sections that follow, we discuss the proposed changes to the regulations in 42 CFR parts 417, 422, 423, and 480 governing the MA and prescription drug benefit programs. To better frame the discussion of the specific regulatory provisions we are proposing, we have structured the preamble narrative by topic area rather than by subpart order. Accordingly, our proposals address the following eight specific goals as foreshadowed in the preceding introduction:

³ See, for example, Wrobel MV, Kling J, Mullainathan S, Shafir E, Vermeulen L (2009). A Shot in the Arm for Medicare Part D: Four Ways for the Government to Boost its Customer Communications. http://www.brookings.edu/papers/2008//media/Files/rc/papers/2008/1120_medicare_kling/1120_medicare_kling.pdf.

⁴ Hargrave E, Piya B, Hoadley J, Summer L, Thompson J (2008). Experiences Obtaining Drugs under Part D: Focus Groups with Beneficiaries, Physicians, and Pharmacists. Final Report Submitted to the Medicare Payment Advisory Commission. National Opinion Research Center.

¹ McFadden D (2006). Free Markets and Fettered Consumers. *The American Economic Review* 96(1), 5–29

² Hanock Y, Rice T, Cummings J, Wood S (2009). How Much Choice is Too Much? The Case of the Medicare Prescription Drug Benefit. *Health Services Research* 44:4; 1157–1168.

- Strengthening our ability to distinguish for approval strong applicants for MMA participation and remove consistently poor performers.
 - Strengthening beneficiary protections.
 - Providing plan offerings with sufficient enrollment and meaningful differences.
 - Improving payment rules and processes.
 - Improving data collection for oversight and quality assessment.
 - Implementing other new policies.
 - Clarifying various sponsor program participation requirements.
 - Implementing corrections and other technical changes.

Several of the proposed revisions and clarifications affect both programs. Within each section, we have provided a chart listing all subject areas that contain provisions affecting the Part C and D programs and the associated regulatory citations that would be revised. Please note that in our discussion of these provisions, we often refer to “sponsoring organizations” to refer to both Medicare Advantage organizations (MAOs) and Part D sponsors.

A. Changes To Strengthen Our Ability To Distinguish for Approval Strong Applicants for Part C and D Program Participation and To Remove Consistently Poor Performers

This section addresses a number of proposals designed to strengthen our ability to approve strong applicants and remove poor performers in the Part C and D programs. Since the implementation of revisions to the MA and initial implementation of the prescription drug programs in January 2006, we have steadily enhanced our ability to measure MAO and PDP sponsor performance through efforts such as the analysis of data provided routinely by sponsors and by our contractors, regular review of beneficiary complaints, marketing surveillance activities, and routine audits. This information, combined with feedback we have received from beneficiary satisfaction surveys, HEDIS data, and information from MAOs and PDP sponsors themselves, has enabled us to develop a clearer sense of what constitutes a successful Medicare organization capable of providing quality Part C and D services to beneficiaries. This information has also allowed us to identify and take appropriate action against organizations that are not meeting program requirements and not meeting the needs of beneficiaries.

As our understanding of Part C and D program operations has deepened over the past 4 years, our use of our authority to determine which organizations are qualified to offer MA and PDP sponsor contracts, evaluate their compliance with Part C and D requirements, and make determinations concerning intermediate sanctions, contract nonrenewals and contract terminations has evolved as well. As set forth below, we are proposing changes and clarifications to our regulations to make certain that all current and potential MAOs and PDP sponsors clearly understand and can reasonably anticipate how we measure sponsor performance, determine when there is noncompliance, and when enforcement actions are warranted. While we are pleased that so many organizations have elected to participate in the Part C and D programs, we have an obligation to ensure that only appropriate organizations are given the responsibility for providing quality medical care and drug coverage to Medicare beneficiaries.

Each year, since contract year 2006, we have solicited applications from organizations seeking to become qualified to enter into Part C or D sponsor contracts. We received hundreds of applications in each of those years. To properly manage a workload of that size, and to ensure that we conduct a fair review of every application, we have adopted an increasingly standardized, computer-based application submission process. At the same time, we have also become increasingly strict in the application of our regulatory authority to limit the number and timing of opportunities for applicants to resubmit materials to cure applications that do not initially demonstrate that the applicant meets Part C or D requirements.

Until 2 years ago, applicants may have found that we would accept as many corrected submissions as the applicants needed to make their materials (usually documents concerning provider/pharmacy networks, subcontracting arrangements, or risk-bearing licenses) consistent with Part C or D requirements. We recognized that this was an inefficient process that afforded some applicants the opportunity to make more re-submissions than others and arguably enabled less well-prepared and qualified applicants to enter the program. To improve the fairness of the application process, and to reduce the burden it imposes on applicants and CMS alike, we have, through our application instructions issued over the last 3 years, clarified to all applicants

that we will only provide three opportunities to submit an approvable contract qualification application to CMS: The initial solicitation response, one courtesy opportunity to correct any identified deficiencies, and a final opportunity during the 10-day cure period provided for specifically in the regulations.

Some organizations have expressed surprise during the last 2 years at our use of our authority to impose strict deadlines and standards of review on applications for qualification as an MAO or PDP sponsor. To reduce the opportunity for confusion about the application process, we are proposing some regulatory clarifications in furtherance of our goal of using a fair and efficient process for ensuring that only truly qualified organizations are offered Part C or D organization contracts. These provisions, described in greater detail below, include requiring applicants to demonstrate that they meet all (not a substantial number) of the Part C and D program requirements, prohibiting applicants from submitting additional curing materials after the expiration of the ten-day period following their receipt of a notice of intent to deny their application, and requiring applicants to submit a nonbinding notice of intent to apply for a Part C or D contract.

Organizations should be aware that we will continue to exercise our authority to consider an organization's past Part C or D contract performance in evaluating whether it should be afforded the opportunity to obtain additional contracts or to serve a larger portion of the Medicare beneficiary population. Additionally, sponsoring organizations should be aware that we rely on data to evaluate compliance with program requirements in a number of ways. For example, we use data to evaluate adherence to requirements in the MMA statute or the Part C and D regulations (for example, retail pharmacy access). We also use data to evaluate adherence to the requirements outlined in our manual chapters and other guidance (for example, customer and provider call center performance standards). Finally, we conduct outlier analysis by comparing the performance across all organizations on a particular Part C or D requirement to identify organizations that appear to be poor performers. The most notable example of this kind of analysis is reflected in our performance metrics (that is, the Medicare Part D Plan Ratings). These ratings represent an effort to make additional information available to the public regarding the price and quality of services for which Medicare makes payments. The Plan

Ratings are located on the Medicare Prescription Drug Plan Finder (MPDPF) Tool at (<http://www.Medicare.gov>) and are designed to provide a clear differentiation of the various Plan offerings to beneficiaries. Organizations receiving less than “good” ratings in any category should anticipate communication from us. Another example is our review of data in the Complaints Tracking Module (CTM), which can be a particularly strong indicator of a sponsor’s inability to perform a required Part C or D function. An abnormally high complaint rate for a particular sponsor will likely prompt us to investigate other sources of information to determine whether the organization is complying with specific Part C or D requirements.

Our efforts are aimed at making certain that we have well-functioning MAOs and PDP sponsors administering Part C and D benefits on our behalf. Just

as we have become more sophisticated in our analysis of sponsor applications and compliance, we also continue to review our sanction and contract termination authority to ensure that we pursue actions when there is sufficient basis to support them. For example, we have developed an annual process for analyzing sponsor performance during the preceding contract year. We review each sponsor’s compliance history, including CMS-issued compliance notices, audit results, and performance ratings (for example, star ratings) to develop a full picture of that sponsor’s ability to deliver Part C and D services to its members. If that picture indicates that a particular sponsor has a significant pattern of poor performance or even isolated incidences of noncompliance with crucial operational requirements (for example, enrollment processing), we will consider

termination or nonrenewal of the contract of that sponsor.

With the clarifications we are proposing to the Part C and D regulations through this proposed rule and the background provided in this preamble section, MAOs and PDP sponsors should now be fully aware that we will continue to apply stricter scrutiny to sponsor qualifications and contract performance as our analytical capabilities and understanding of industry best practices improves. As the Part C and D programs have now reached a certain level of maturity and organizations’ strong interest in participating in the programs has been established, it is appropriate for us to use the authority and evidence at our disposal to make certain that beneficiary plan choices are characterized more by their quality than their quantity. These provisions are described in detail in Table 1.

TABLE 1—PROVISIONS STRENGTHENING OUR ABILITY TO DISTINGUISH FOR APPROVAL STRONG APPLICANTS AND TO REMOVE CONSISTENTLY POOR PERFORMERS

Provision	Part 422		Part 423	
	Subpart	Section	Subpart	Section
Notice of Intent to Apply	Subpart K ..	§ 422.501	Subpart K ..	§ 423.502.
Application Standards	Subpart K ..	§ 422.502	Subpart K ..	§ 423.503.
Compliance Measures/Analysis	Subpart K ..	§ 422.502	Subpart K ..	§ 423.503.
Compliance Programs	Subpart K ..	§ 422.503(b)(4)(vi)	Subpart K ..	§ 423.504(b)(4)(vi).
Network Adequacy of Coordinated Care and Network-Based Private-Fee-For-Service plans under Part C.	Subpart C ..	§ 422.112	N/A	N/A.
Clarify programmatic elements that are “deemable”.	Subpart D ..	§ 422.156(b)(7), § 422.156(f)	Subpart D ..	§ 423.165(b), § 423.165(f).
Procedures for termination and Nonrenewals: Part C and D.	Subpart K ..	§ 422.510(c)(1), § 422.506(b)(3)	Subpart K ..	§ 423.509(c)(1), § 423.507(b)(3).
Intermediate Sanctions: Procedures for imposing civil and money penalties.	Subpart O ..	§ 422.756	Subpart O ..	§ 423.756.
Contract Termination	Subpart K ..	§ 422.510(a)	Subpart K ..	§ 423.509(a).
Proper request for hearings	Subpart N ..	§ 422.662	Subpart N ..	§ 423.651.
Burden of Proof, Standard of Proof, Standard of Review and Conduct of Hearing.	Subpart N ..	§ 422.660, § 422.676(d)	Subpart N ..	§ 423.650, § 423.658(d).
Postponement of effective date of determination when a request is being filed.	Subpart N ..	§ 422.664	Subpart N ..	§ 423.652.
Extending timeframe for contract determination hearings.	Subpart N ..	§ 422.670	Subpart N ..	§ 423.655.
Appeal times: Require each party provide witness list and documents 5 calendar days before hearing.	Subpart N ..	§ 422.682	Subpart N ..	§ 423.661.
Appeal times: Require request for a review by the administrator must be received with 15 days after receipt of hearing decision.	Subpart N ..	§ 422.692(a)	Subpart N ..	§ 423.666(a).
Contract redeterminations and reopening	Subpart N ..	§ 422.696	Subpart N ..	§ 423.668.
Mutual termination of contract	Subpart K ..	§ 422.503(b)(6)	Subpart K ..	§ 423.504(b)(5).

1. Require Notice of Intent To Apply Under Part C and D Within the Application Requirements (§ 422.501 and § 423.502)

Subpart K of part 422 and subpart K of part 423 set forth the requirements for contracts with MA Organizations and Part D sponsors including application

procedures. Section 1871(a)(1) of the Act authorizes us to prescribe such regulations as may be necessary to carry out the administration of the Medicare program. We propose using that authority to establish an administrative requirement for both the Part C and D programs related to the submission to us

of applications to qualify as MA and PDP sponsor contractors.

Beginning with the applications for the 2009 contract year, the Medicare Advantage, Part D Prescription Drug benefit, and Employer/Union-Only Group Waiver Plan (Direct Contract or “800 Series”) sponsor applications are

submitted via a paperless process. Each application is completed through the CMS Health Plan Management System (HPMS). As a result of the fully electronic submission process and restrictions on access to HPMS, every applicant must complete a Notice of Intent to Apply as described in the HPMS memo dated October 10, 2008. This includes current contractors seeking to expand their organization's service area, and current contractors adding a Special Needs Plan (SNP) or an Employer Group/Union-Sponsored Waiver Plan (EGWP) to their existing contract.

The Notice of Intent to Apply provides us with critical information for generating a pending contract number and providing User ID connectivity. Submitting a Notice of Intent to Apply does not bind that organization to submit an application for the following year. However, without a pending contract number and completed CMS User ID connectivity, an organization will not be able to access the appropriate modules in HPMS to complete the application materials. We propose codifying in § 422.501 and § 423.502 our existing guidance that initial applicants and existing contractors seeking to expand complete a nonbinding Notice of Intent to Apply.

2. Application Requirements (§ 422.501(c) and § 423.502(c)) and Evaluation and Determination Procedures for Determining Whether Applicants Are Qualified for a Contract Under Parts C and D (§ 422.502 and § 423.503)

Subpart K of Part 422 and subpart K of Part 423 set forth the requirements for contracts with MA organizations and Part D sponsors, respectively, including application procedures. Section 1860D-12(b)(3) of the Act states that we must apply certain specified provisions of section 1857 of the Act including the procedures for termination in section 1857(h) of the Act in the same manner as they apply to contracts under section 1857(a) of the Act. Therefore, we are making a single proposal that applies to both MA organizations and Part D sponsors related to our application evaluation procedures and appeals of our determinations regarding applications.

During the first four years of the Medicare Advantage and Part D programs, several unsuccessful applicants contested our denial of their applications for MA organization or Part D sponsor contracts. At hearings, some of those applicants were successful in arguing that the regulations were not clear in stating that an applicant needed

to demonstrate that it met all program requirements to qualify for a contract. Accordingly, we are proposing to revise § 422.502 and § 423.503 to make it explicit that we will approve only those applications that demonstrate that they meet all (not substantially all) Part C and D program requirements.

The application requirements and evaluation and determination procedures for MA organizations and Part D sponsors are set forth in subpart K of Parts 422 and 423, respectively. The application process in each instance requires an applicant to submit for CMS review a combination of attestations that it will comply with stated program requirements, as well as contracts with organizations the applicant has contracted with to perform key Part C or D functions, evidence of the applicant's risk-bearing licenses, and data documenting that the applicant can provide its members access to Part C and D services consistent with the programs' requirements. As we have proposed to clarify at § 422.501(c)(1) and (2), § 422.502(a)(2), § 423.502(c)(1) and (2), and § 423.503(a)(2), we require that applicants demonstrate that they meet all requirements outlined in the MA organization and Part D sponsor applications.

Under the current regulations at § 422.502(a)(1) and § 423.503 (a)(1), we evaluate an entity's application on the basis of information contained in the application itself and any additional information that we obtain through onsite visits, publicly available information, and any other appropriate procedures. We propose to simplify and clarify the process by modifying § 422.502(a)(1) and § 423.503(a)(1) and limiting the evaluation of an entity's application to information contained in the application and any additional information that we obtain through onsite visits. Limiting our review to this information ensures that we will afford all applicants (numbering in the hundreds each of the last four years) a fair and consistent review of their qualifications. Organizations can be assured that we will not consider additional sources of information regarding one applicant's qualifications that we do not consider for others.

We are also proposing a clarification of our authority to decline to consider application materials submitted after the expiration of the 10-day period following our issuance of a notice of intent to deny an organization's contract qualification application. Under § 422.502(c) and § 423.503(c), we notify applicants of our determination on the application and the basis for the

determination. If the applicant does not appear qualified to contract as an MA organization or Part D sponsor and has not provided enough information to permit us to evaluate the application, the applicant receives a notice of intent to deny the application and a summary for the basis for the finding. As provided in § 422.502(c)(2) and § 423.503(c)(2), within 10 days from the date of the notice, the applicant can respond in writing to the issues or other matters that were the basis for our findings and revise its application to correct any deficiencies.

The purpose of the proposed regulatory change is to clarify that information submitted after 10 days from the notice will under no circumstances be reviewed for the purpose of approving an application. Further, consistent with the proposed revisions to § 422.650(b)(2) and § 423.660(b)(2), which are discussed elsewhere in this proposed rule, the applicant would not be permitted to submit additional revised application material to the Hearing Officer for review should the applicant elect to appeal the denial of its application. To allow for the submission and review of such information as part of the hearing would, in effect, extend the deadline for submitting an approvable application. Moreover, the proposed change would further clarify the standard for the disposition of applications for which either revisions are not provided within the 10 days or are inadequate.

Specifically, we propose to clarify § 422.502(c)(2) and § 423.503(c)(2) by adding a new paragraph (iii) to establish that if we do not receive a revised application within 10 days from the date of the intent to deny notice, or if after timely submission of a revised application the applicant still appears unqualified to contract as an MA organization or Part D sponsor and/or has not provided enough information to allow us to evaluate the application, we will deny the application.

3. Deny Contract Qualification Applications Based on Past Contract Performance (§ 422.750 and § 423.750)

As described in § 422.502(b) and § 423.503(b), we may deny an application based on the applicant's failure to comply with the terms of a prior contract with CMS even if the applicant currently meets all of the application requirements. However, we propose to modify § 422.502(b) and § 423.503(b) to state that we will review past performance across all of the contracts held by the applicant. The provision as currently drafted mentions a "prior contract" with CMS. Today,

contracts are “evergreen” and some organizations hold multiple MA and/or PDP sponsor contracts; therefore the concept of “prior contract” is outdated, as the prior performance issues could have occurred in any other contract currently or formerly held by an applicant. Therefore, we propose to revise the language in § 423.503(b) and § 422.502(b) to refer to “any current or prior contract” held by the organization, instead of the current language referring to a “previous year’s contract.” We also propose to clarify that the period that will be examined for past performance problems be limited to those identified by us during the 14 months prior to the date by which organizations must submit contract qualification applications to CMS. Fourteen months covers the time period from the start of the previous contract year through the time that applications are received for the next contract year.

Indicia of performance deficiencies that might lead us to conclude that an organization has failed to comply with a current or prior contract include, but are not limited to, poor performance ratings as displayed on the Medicare Options Compare and MPDPF web sites; receipt of requests for corrective action plans (CAPs) unrelated to an audit (as these types of CAPs generally involve direct beneficiary harm); and receipt of one or more other types of noncompliance notices from CMS (for example, notices of noncompliance or warning letters).

Additionally, as indicated by the changes to § 422.503(b), § 422.508(c), § 423.504(b), and § 423.508(e), we consider withdrawal of Part C or D operations from some or all of an organization’s newly contracted service area prior to the start of a benefit year (through mutual termination or otherwise) an indication of poor performance. Such a situation can arise when, for example, an organization, after it has signed its Medicare contract for the upcoming program year, loses a contract with a significant number or type of providers, jeopardizing its ability to provide its members adequate access to services. Also, an organization may suddenly face financial difficulties that threaten its ability to offer the benefit packages approved by CMS throughout the upcoming contract year. In such instances, we could simply leave the contract in place and take enforcement actions against the organization. Under such an approach, we would knowingly be permitting beneficiaries to remain enrolled with an organization that cannot effectively deliver the benefit. Instead, we act(s) in the best interests of the beneficiaries by

agreeing with the organization to terminate its contract and work(s) with the organization to make certain that beneficiaries receive uninterrupted access to Medicare services through another MA organization, PDP sponsor, or original Medicare. But for our acting to protect beneficiaries by agreeing to the contract termination, the organization would have faced significant compliance and enforcement actions once its failure to comply with program requirements became apparent. Also, the organization’s failure to conduct the proper due diligence on its contracted provider network or its finances represents itself a significant failure to have in place the administrative capability to operate a Medicare benefit plan worthy of compliance and enforcement actions. Accordingly, we believe(s) it is appropriate to consider an organization’s withdrawal from its contract prior to the start of the benefit year to be a strong indication of poor performance worthy of our consideration under § 422.750 and § 423.750.

We will review performance in accordance with these examples and other evidence of noncompliance, and will deny applications for initial contracts and service area expansions on the basis of noncompliant past performance. By specifically providing these examples and clarifying that we intend to exercise this authority, we believe that organizations will be motivated to enhance their compliance operations in order to avoid being out of compliance with program requirements, and this will significantly deter noncompliance leading to improved overall performance of organizations in the Part C and D programs.

4. Use of Data To Evaluate Continued Ability To Act as a Qualified Sponsoring Organization Under Parts C and D (§ 422.504, and § 423.505)

Sections 1857(e)(1) and 1860D–12(b)(3)(D) of the Act provide broad authority for the Secretary to add terms to the contracts with MA and Part D sponsors including terms that require the sponsor to provide the Secretary “with such information * * * as the Secretary may find necessary and appropriate.” Under that authority, we established § 422.516 and § 423.514, Reporting Requirements. Consistent with sections 1857(a) and 1860D–12(b)(1) of the Act, we established that we will oversee an MA organization’s and Part D sponsor’s continued compliance with Part C and Part D requirements under § 422.502(d)(1) and § 423.503(d)(1).

Some of the data acquired through § 422.516 and § 423.514 are used for the purpose of monitoring an organization’s or sponsor’s continued compliance with MA and/or Part D requirements. For example, under § 423.514(a)(5), Part D sponsors must have an effective procedure to develop, compile, evaluate, and report to CMS particular matters, such as low income subsidy (LIS) contract data, that we require. At the contract level, the sponsor’s LIS data is compared to our LIS data and a match rate is calculated. Under our guidance, the match rate between our data and the sponsor’s should exceed 95 percent. Sponsors who fail to exceed the 95 percent match rate are notified of their noncompliance and are expected to come into compliance with Part D instructions. In some instances, we may use an outlier analysis to determine a MA organization’s or Part D sponsor’s performance relative to industry standards established by the performance of all the other organizations and sponsors as described earlier in the preamble in our discussion of the development of our policies concerning the awarding, monitoring, and enforcement of Medicare contracts. For example, Part D plans report grievance data to CMS. We conduct outlier analysis to identify plans with the highest numbers of reported grievances for the purpose of identifying plans needing some type of compliance action. To conduct these types of outlier analysis, we usually perform the following steps:

- Develop a data distribution—data values ordered from low to high.
- Determine the maximum and minimum data values.
- Determine the range (maximum–minimum).
- Determine the outlier threshold—

When conducting an outlier analysis, we typically identify sponsors typically in the highest (or lowest) 5 percent of comparable sponsors (for example, compare PDPs to PDPs).

We also use the Performance Metrics (Plan Star Ratings), some of which are determined by relative ranking, for oversight and monitoring purposes to ensure plan quality. As stated in the 2009 Call Letter, organizations and sponsors with less than “good” ratings should expect to be the subject of our monitoring and compliance actions. Likewise, if after an analysis of data submitted under § 422.516 or § 423.514 an organization’s or sponsor’s performance is found to be an outlier based on relative ranking, the organization or sponsor may be considered out of compliance with MA and Part D requirements.

We propose to add paragraphs § 422.504(m)(1) and (2) and § 423.505(n)(1) and (2) to make explicit our existing authority to find organizations or sponsors out of compliance with MA and/or Part D requirements when the organization's or sponsor's performance fails to meet performance standards articulated in statutes, regulations, and guidance or when an organization's or sponsor's performance represents an outlier relative to the performance of other organizations or sponsors.

5. Compliance Programs Under Parts C and D (§ 422.503(b)(4)(vi) and § 423.504(b)(4)(vi))

Section 1857(a) of the Act provides the Secretary with the authority to enter into contracts with MA organizations and section 1860D–12(b)(1) of the Act provides the Secretary with the authority to enter into contracts with PDP sponsors. The current regulatory provisions provide that any entity seeking to contract as an MA organization or PDP sponsor must have administrative and management arrangements satisfactory to us as demonstrated by (among other requirements) having a compliance plan that consists of seven basic elements. These seven elements of the compliance plan outline fundamental requirements such as written policies and procedures, a compliance officer and committee that is accountable to senior management, effective compliance training and communication, enforcement of disciplinary standards, and procedures for internal monitoring and auditing and ensuring prompt responses to detected offenses. In addition, a compliance plan must include measures to detect, correct, and prevent fraud, waste, and abuse.

Compliance programs have long been recognized as key to achieving adherence with contract requirements and to protecting against fraud, waste, and abuse. The recent focus on the importance of these programs has been heightened not only by CMS through our ongoing audit and oversight efforts but also by several of our oversight bodies. For example, over the last several years, the U.S. Department of Health and Human Services Office of Inspector General (OIG) and the Government Accountability Office (GAO) have each focused specific oversight efforts on MA organizations' and PDP sponsors' compliance programs and have requested that we take actions to evaluate and oversee these programs to ensure entities have effective programs in place. Similarly, like the Medicare Part C and D

programs, other state programs, including the State of New York Medicaid program, now require effective compliance programs as a condition of participation.

Our recent experience is that some sponsoring organizations have instituted a compliance plan that appears to meet the minimum requirements of our regulations, but may not have an effective compliance program. Other sponsoring organizations seem to legitimately grapple with how best to implement the regulatory requirements within their organization and which particular actions on their part will meet our requirements.

We propose to stress the importance of sponsoring organization's implementing and maintaining robust compliance programs by modifying the language at § 422.503(b)(4)(vi) and § 423.504(b)(4)(vi) to explicitly provide clarification as to what will constitute an "effective" compliance program prior to contracting with CMS. We are also proposing to further clarify existing policy by modifying current language and/or adding language in support of each of the elements of an effective compliance plan in order to assist sponsoring organizations with implementing more effective compliance programs.

In the first element concerning the overall requirement to have written policies and procedures, we are proposing to further clarify existing policy by adding language at § 422.503(b)(4)(vi)(A) and § 423.504(b)(4)(vi)(A) that these policies must describe compliance expectations as embodied in the standards of conduct, implement the operations of the compliance program, provide guidance to others, identify how to communicate compliance issues to compliance personnel, describe how compliance issues are investigated and resolved and include a policy of non-intimidation and non-retaliation.

In the second element concerning the requirement to have a compliance officer and committee accountable to senior management, we are proposing to further clarify existing policy by adding language at § 422.503(b)(4)(vi)(B) and § 423.504(b)(4)(vi)(B) that the compliance officer and committee must periodically report directly to the governing body (for example, Board of Directors) and that body must be knowledgeable about the compliance program and exercise reasonable oversight over the implementation and effectiveness of the program. The governing body's direct involvement with and oversight of the compliance program is instrumental in fulfilling this

requirement and achieving an effective compliance program. Our recent experience with some sponsoring organizations has indicated that Boards of Directors may not be sufficiently aware or may have limited information about their organization's compliance programs or compliance issues. In deciding how often the compliance officer and committee must directly report to the Board of Directors, sponsoring organizations must consider many factors, including but not limited to: the size of the organization, the number of compliance problems, whether there is an emergency that calls for the Board's attention, and whether the sponsoring organization is under an intermediate sanction. Our proposed language further clarifies existing policy related to this requirement for senior management to be sufficiently engaged, informed, and to exercise appropriate governance over the organization's compliance program.

In the third element concerning the requirement to have effective training and education, we are proposing to further clarify existing policy by adding language at § 422.503(b)(4)(vi)(C) and § 423.504(b)(4)(vi)(C) that includes several key groups and individuals (the chief executive or other senior administrator, managers, and governing body members) among the sponsoring organization's employees that are required to have compliance training and education. Because these employees have specific governing and oversight responsibilities, we believe it is important to clarify these requirements. We are proposing to further clarify existing policy by adding language that also clarifies that this training must occur at a minimum annually and must be made a part of the orientation for a new employee, new first tier, downstream and related entities, and new appointment to a chief executive, manager or governing body member.

In the December 5, 2007 **Federal Register**, we published the "Medicare Program; Revisions to the Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals and Intermediate Sanctions Process" final rule (72 FR 68700). In the December 5, 2007 final rule, we established that compliance plans for sponsoring organizations must include training and education and effective lines of communication between the compliance officer and the sponsoring organization's employees, managers, and directors as well as their first tier, downstream, and related entities.

Since publication of the December 5, 2007 final rule, it has become apparent that application of training about fraud,

waste, and abuse to the MA organizations' first tier, downstream, and related entities may be redundant of the certification made when these entities submit enrollment applications to become Medicare physician and non-physician practitioners, institutional providers, and suppliers. Medicare practitioner enrollment applications require that applicants certify to having read and understood the Penalties for Falsifying Information contained in the application and that the applicant will not present or cause to present a false claim to Medicare. Section 422.204(b)(3) requires that basic benefits offered by MA organizations be offered through providers and suppliers who meet applicable requirements of Title XVIII and Part A of Title XI of the Act. Providers of services must have a provider agreement with us that permits them to provide services under original Medicare. Requiring an additional fraud, waste, and abuse certification as was clarified in the response to comments in the December 5, 2007 final rule imposes an additional unnecessary burden on these Medicare providers. Therefore, we are proposing to modify this paragraph to state that providers who have met this requirement through enrollment into the Medicare program are deemed to have met this training and education requirement. More specifically, we are proposing to clarify existing policy by adding language at § 422.503(b)(4)(vi)(C) specifying that MA organizations whose first tier, downstream, and related entities have met the fraud, waste and abuse certification requirements are deemed to have met the training and educational requirements for fraud, waste, and abuse. We are not proposing similar deeming language at § 423.504(b)(4)(vi)(C) because these certification requirements do not currently apply to Part D first tier, downstream, or related entities.

The current requirement for training in fraud, waste, and abuse of first tier, downstream, and related entities creates another potential problem. A particular pharmacy or other provider may contract with dozens of MA or PDP plans, each of which is required by the existing language, read literally, to provide the required training to the pharmacy, or other provider, and its staff. Clearly, we do not intend to require duplicative training. We therefore seek comment on whether or how best to rephrase the existing language to clarify this point, while still ensuring that our requirement is met with respect to each first tier, downstream, and related entity. One

option might be that the plan sponsor "assures" or "obtain an assurance" that the first tier, downstream, and related entity has received such training, but this leaves open the issue of who would then actually provide the needed training. We understand that some plans are arranging fraud, waste, and abuse collaborative training efforts and we welcome this. Another option might be to leave existing language unchanged, but issue interpretive guidance on this point. We request workable suggestions to assure that our objective is met, while eliminating unnecessary duplication.

In the fourth element concerning the requirement to have effective lines of communication, we are proposing to further clarify existing policy by adding language at § 422.503(b)(4)(vi)(D) and § 423.504(b)(4)(vi)(D) that requires that these lines of communication are confidential and accessible to all and allow for compliance issues to be reported anonymously and in good faith as issues are identified.

In the fifth element concerning the requirement to have enforcement of standards through well-publicized disciplinary guidelines, we are proposing to further clarify existing policy by adding language at § 422.503(b)(4)(vi)(E) and § 423.504(b)(4)(vi)(E) that more specifically describes that these guidelines must be implemented to include policies that articulate expectations for reporting issues and their resolution, identify noncompliance or unethical behavior, and provide for timely, consistent and effective enforcement of the standards when noncompliance or unethical behavior is detected.

In the sixth element concerning the requirement to have procedures for internal monitoring and auditing, we are proposing to further clarify existing policy by modifying the current language at § 422.503(b)(4)(vi)(F) and § 423.504(b)(4)(vi)(F) to more specifically describe that an effective system for routine monitoring and identification of compliance risks includes internal monitoring and audits and, as appropriate, external audits, in order to evaluate the organization's compliance with our requirements and overall effectiveness of the compliance program. These audits should include the sponsoring organization's first tier entities.

In the seventh element concerning the requirement to have procedures for ensuring prompt response to detected offenses and development of CAPs, we are proposing to further clarify existing policy by modifying the current language at § 422.503(b)(4)(vi)(G) and

§ 423.504(b)(4)(vi)(G) to more specifically describe the implementation of a system for promptly responding to compliance issues as they are raised, investigating potential compliance problems identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence and ensuring ongoing compliance with our requirements.

6. Network Adequacy of Coordinated Care and Network-Based Private Fee-for-Service Plans Under Part C (§ 422.112)

Section 1852(d)(1)(A) of the Act establishes that an organization offering an MA plan may select the providers from whom the benefits under the plan are provided so long as the organization makes such benefits available and accessible to each individual electing the plan within the plan service area with reasonable promptness and in a manner which ensures continuity in the provision of benefits. The requirements of section 1852(d)(1)(A) of the Act are implemented at § 422.112(a)(1), which provides that a coordinated care plan must maintain a network of appropriate providers that is sufficient to provide adequate access to covered services to meet the needs of the population served.

To determine if a proposed health care delivery network of an MA plan adequately makes health care services available and accessible, it has been our practice when initially approving and when reviewing to compare the proposed network with the prevailing community patterns of health care delivery in the service area of the plan. We have also used as a rough benchmark a maximum access to providers of 30 minutes/30 miles. We would be interested in comments regarding our proposed criteria for developing standards for the network adequacy of MA plans. We are in the process of developing an automated system for reviewing network adequacy on a continuing basis based on the elements that we determine define community patterns of health care delivery. In this system, MAOs offering MA plans would submit data to us through the HPMS system specifying the access and availability of its proposed provider networks. This information would be analyzed and compared through electronic mapping software against our access standards for a given geographical area to confirm whether the proposed provider network meets our access and availability standards.

Given that we are developing this automated system, we believe it is

appropriate to more explicitly define how we determine network adequacy. To that end, we propose using our authority under section 1852(d)(1)(A) of the Act to include more specific criteria that we will apply in defining community patterns of care in order to determine if a network offered by an MA plan meets Medicare access and availability requirements. We also propose applying these more specific criteria to the proposed provider networks of both coordinated care and PFFS plans that are intending to meet Medicare access to services requirements, in whole or in part, through a network of direct contracting providers.

Our operational experience has demonstrated that the concept of community patterns of health care delivery provides a useful industry standard benchmark for measuring a proposed provider network because it allows for varying geographical and regional conditions to be taken into consideration. For example, plans operating in rural rather than urban counties will necessarily face different market conditions in terms of the number and specialties of providers available and their willingness to contract with the plan.

However, given the lack of specificity regarding how we determine if a given provider network meets Medicare access and availability requirements in § 422.112(a)(1) as currently drafted, we believe it is important to amend that section of our regulations to describe how we will include the elements of the prevailing community patterns of health care delivery in its evaluations of provider networks. We believe the proposed changes will make the standards of community patterns of care more transparent and consistent across the country. The proposed changes are consistent with the elements that will be used by the automated system we are developing to assess network adequacy.

Specifically, we propose to add paragraph (a)(10) to amend § 422.112 to specify the factors comprising community patterns of health care delivery that we will use as a benchmark in evaluating a proposed MA plan health care delivery network. Under proposed § 422.112(a)(10), these factors would include, but not be limited to—

- The number and geographical distribution of eligible health care providers available to potentially contract with an MAO to furnish plan covered services within the proposed service area of the MA plans;
- The prevailing market conditions in the service area of the MA plan.

Specifically, the number and distribution of health care providers contracting with other health care plans (both commercial and Medicare) operating in the service area of the plan;

- Whether the service area is comprised of rural or urban areas or some combination of the two;
- Whether the MA plan's proposed provider network meets Medicare time and distance standards for member access to health care providers including specialties; and
- Other factors that we determine to be relevant in setting a standard for an acceptable health care delivery network in a particular service area.

We plan to further define through subregulatory guidance (for example the Call Letter) how we will operationalize these provisions. For example, as previously noted, we have in the past used as a rough benchmark a maximum access to provider ratio of 30 minutes/30 miles to determine “network adequacy.” We solicit comment on whether these regulatory provisions are sufficiently clear, and whether clarification should be provided through regulation or subregulatory guidance, such as the annual Call Letter.

7. Deemable Program Requirements Under Parts C and D (§ 422.156(b)(7), § 422.156(f), § 423.165(b), and § 423.165(f))

We are proposing to clarify which regulatory requirements are “deemable” for MA organizations that offer prescription drug benefit programs. Sections 1852(e)(4) and 1860D–4(j) of the Act provide that we can authorize approved accrediting organizations (AOs) to accredit MA organizations and Part D sponsors, and deem such entities to have met our program requirements, as long as the standards the AO uses to evaluate the performance of the organizations and plan sponsors meet or exceed our own performance assessment standards. The statute also dictates which performance standards we can allow an AO to evaluate in the place of CMS. Those standards that we permit AOs to survey for, rather than CMS, are referred to as “deemable” program requirements.

The current regulations state that the Part D prescription drug benefit program is a deemable requirement for MA organizations that offer prescription drug benefits. We believe that this language does not precisely reflect the requirements that are listed as deemable in the statute. Therefore, we are proposing to modify § 422.156(b)(7) to refer to the list of deemable requirements for Part D sponsors set out at § 423.165(b)(1) through (b)(3), as we

believe this cross reference is a more accurate reflection of the specific program requirements that are deemable per section 1860D–4(j) of the Act for MA organizations that offer prescription drug benefits.

In § 422.156(f) and § 423.165(f), we are proposing to clarify the extent of our authority under the deeming program. The regulation currently states that we retain our authority to initiate enforcement actions against MA organizations or Part D sponsors that we determine, on the basis of its own survey, or the survey of an accrediting organization, no longer meet the Medicare requirements for which deemed status was granted. We believe that this language is unduly limiting and does not comport with the statute. Section 1852(e)(4)(D) of the Act states nothing in section 1852(e)(4) of the Act shall be construed to limit our authority under section 1857 of the Act, which encompasses much more than enforcement actions. Therefore, we are proposing to revise the language in § 422.156(f) and § 423.165(f) to more closely match the authority granted by the statute, which is to state that we retain authority to impose intermediate sanctions and civil money penalties (CMPs), initiate contract terminations, and perform evaluations and audits of an organization's records, facilities and operations, notwithstanding the deeming provisions.

We plan to further define through subregulatory guidance how we will operationalize these provisions. We solicit comment on whether these regulatory provisions provide sufficient clarity. If not, we solicit comment on whether clarification should be provided through regulation or subregulatory guidance, such as the annual Call Letter.

In § 423.165(b), we are proposing to delete paragraph (b)(4) from the items listed as deemable program requirements. The regulation currently states that a program to protect against fraud, waste, and abuse is a deemable program requirement. We believe that including this in the list of deemable requirements was an error, as the statute does not list a program to protect against fraud, waste, and abuse as one of the programmatic areas that is deemable. Therefore, we are proposing to remove programs to protect against fraud, waste, and abuse from the list of deemable programmatic requirements.

8. Modify the Corrective Action Plan (CAP) Process as it Relates to Procedures for Termination and Nonrenewal of a Part C or D Contract by CMS (§ 422.506(b)(3), § 422.510(c)(1), § 423.507(b)(3), and § 423.509(c)(1))

Sections 1857(h) and 1860D–12(b)(3)(F) of the Act provide that the Secretary may terminate a contract with an MA organization or PDP sponsor in accordance with formal investigation and compliance procedures established by the Secretary under which the sponsoring organizations are to be provided with reasonable notice and opportunity for hearing and reasonable opportunity to develop and implement a CAP to correct the deficiencies that were the initial basis for termination prior to terminating the contract. These statutory provisions further provide, under sections 1857(h)(2) and 1860D–12(b)(3)(F) of the Act, that these procedures shall not apply if the Secretary determines that a delay in termination, resulting from compliance with these procedures prior to termination, would pose an imminent and serious risk to the health of individuals enrolled with the sponsoring organization.

Under this statutory authority, we issued the December 5, 2007 final rule that detailed timeframes for the development and implementation of CAPs prior to an issuance of a notice of intent to terminate or nonrenew a CMS contract. These regulations, codified at § 422.506(b)(3), § 422.510(c)(1), § 423.507(b)(3), and § 423.509(c)(1), currently require us to provide sponsoring organizations with 45 calendar days from the date of our request, to develop and submit a CAP prior to CMS issuing a notice of intent to terminate or nonrenew a contract to the sponsoring organization. In addition, the current regulations provide that if, after our review, this first CAP submission is determined unacceptable, the sponsoring organization will be provided an additional 30 calendar days to submit a revised CAP to CMS for review. Under these current provisions, once we determine the CAP acceptable, we are then required to notify the sponsoring organization of the deadline by which the CAP must be fully implemented. We must then assess whether successful implementation occurred. It is only after exercising these protracted procedures that we may issue a notice of intent to terminate or nonrenew a contract to the sponsoring organization in instances when we determine that successful implementation of the CAP has not

occurred and/or the deficiencies have not been fully corrected.

Since the implementation of the December 5, 2007 final rule, we have determined that some modification is required of our overall approach to our compliance procedures, particularly in situations when serious and/or repeated compliance deficiencies are identified. More specifically, we have concluded that the compliance procedures and timeframes set forth in § 422.506(b)(3), § 422.510(c)(1), § 423.507(b)(3), and § 423.509(c)(1) related to notice and opportunity to develop and implement corrective actions could be improved to more effectively assist us and sponsoring organizations in achieving timely, efficient, and effective correction of identified underlying contract compliance deficiencies. These current compliance procedures require us to focus our internal oversight resources and expertise on reviewing and approving “how” sponsoring organizations will correct their deficiencies rather than utilizing our resources and expertise more effectively and efficiently to review information submitted by sponsoring organizations to determine if the underlying deficiencies have actually been corrected. For example, if the deficiency cited was for misclassification of appeals versus grievances, current practice requires a sponsoring organization to develop a written plan on how it will fix the misclassification problem. Then the sponsoring organization must submit the plan to us for review and approval before it would be allowed to implement the plan. Rather than focusing on the plan or process that the sponsoring organization developed, we instead, should focus on reviewing data to determine if the sponsoring organization has actually fixed the problem and is classifying appeals and grievances appropriately.

Similarly, under the current compliance procedures, sponsoring organizations potentially expend significant resources and expertise responding to requests from us for plans about how they will correct deficiencies as opposed to expending efforts on correcting the deficiencies identified by us and providing sufficient evidence that the identified deficiencies have been corrected. Given that sponsoring organizations have varying business models, levels of resources, and expertise, it is particularly challenging for us to be the decision-maker as to whether one operational plan of correction under a particular operational business model versus another will most effectively correct

identified deficiencies and achieve particular compliance outcomes.

Therefore, we believe our compliance procedures need to shift from focusing on the submission of plans for our review and approval that merely outline a process for how deficiencies will be corrected to a focus on requiring plans to demonstrate that particular outcomes have been achieved, for example, that deficiencies have actually been corrected. We are proposing to eliminate the existing language contained in regulations at § 422.506(b)(3), § 422.510(c)(1), § 423.507(b)(3), and § 423.509(c)(1) that requires CAPs to be submitted for our approval prior to us issuing a notice of intent to terminate or nonrenew a contract.

We are proposing instead to add new provisions at § 422.506(b)(3), § 422.510(c)(1), § 423.507(b)(3), and § 423.509(c)(1) that captures the outcome-oriented approach which is currently incorporated in our day-to-day ongoing contract compliance and oversight activities. Under this approach, we are proposing to add new provisions which state that before providing a notice of intent to terminate or nonrenew a contract, we will provide the sponsoring organization with a notice of its deficiencies and afford it the opportunity to develop and implement a CAP to correct these deficiencies. We are also proposing that the sponsoring organization is solely responsible for the identification, development, and implementation of its CAP and for demonstrating to us that the underlying deficiencies have been corrected within the time period afforded under the notice and opportunity for corrective action.

All sponsoring organizations are assigned a CMS account manager whose primary responsibility consists of day-to-day monitoring and oversight of that organization. In addition to these account management monitoring and oversight activities, we conduct other oversight activities based on data and information collected from sponsoring organizations and from other relevant sources. As a part of these ongoing overall monitoring and oversight activities, sponsoring organizations routinely receive written notification of their compliance deficiencies, including but not limited to, notices of noncompliance, warning notices, and requests for corrective actions. These ongoing contract monitoring and oversight processes are designed to proactively prevent, detect, and respond to compliance deficiencies at the lowest level of occurrence by providing sponsoring organizations with ongoing notification and information from CMS

about the current status of any identified compliance deficiencies that come to our attention and an opportunity to correct where appropriate. As a result, in many instances sponsoring organizations will receive written notification of noncompliance and opportunities to correct any deficiencies arising from the above-described day-to-day monitoring and oversight procedures. Therefore, in most cases the sponsoring organization will have been made fully aware of its deficiencies before CMS provides it with the notice and opportunity to implement a CAP that must be afforded prior to CMS issuing a notice of intent to terminate or nonrenew a contract under sections 1857(h) and 1860D–12(b)(3)(F) of the Act.

In addition to these proposals, we are proposing to amend the existing language at § 422.506(b)(3), § 422.510(c)(1), § 423.507(b)(3), and § 423.509(c)(1) that sets forth the specific timeframes afforded sponsoring organizations for the development and implementation of a CAP prior to CMS issuing a notice of intent to terminate or nonrenew.

Based on our experience under our ongoing contract compliance and oversight processes and our new outcome-oriented approaches to contract oversight and compliance, we have concluded that affording sponsoring organizations at least 30 calendar days to develop and implement a CAP prior to issuing the notice of intent to terminate or nonrenew is a sufficiently reasonable opportunity under the statutory authority afforded. We will consider the nature and extent of the particular compliance deficiencies and other relevant factors such as whether or not the deficiencies are isolated or repeated and longstanding, and whether or not the entity has been afforded a prior notice and opportunity to correct in reaching a decision whether it may be appropriate for the MAO or Part D Sponsor to be afforded more than 30 days to correct the identified deficiencies.

Thus, we are proposing to amend § 422.506(b)(3), § 422.510(c)(1), § 423.507(b)(3), and § 423.509(c)(1) to afford sponsoring organizations at least 30 calendar days to fully implement a CAP and to demonstrate to CMS that the underlying deficiencies have been corrected.

9. Procedures for Imposing Intermediate Sanctions and Civil Money Penalties Under Parts C and D (§ 422.756 and § 423.756)

Sections 1857(g) and 1860D–12(b)(3)(E) of the Act provide the Secretary the ability to impose intermediate sanctions on sponsoring organizations. Intermediate sanctions under these statutory provisions consist of suspension of enrollment, suspension of payment and CMPs. Sections 1857(g)(2)(B) and 1860D–12(b)(3)(E) of the Act that specifically govern enrollment suspensions require the intermediate sanctions to remain in place until the Secretary is satisfied that the basis for the sanction determination has been corrected and is not likely to recur. Additionally, under sections 1857(e)(1) and 1860D–12(b)(3)(D) of the Act, sponsoring organizations are required to provide the Secretary with such information as the Secretary may find necessary and appropriate. Current regulations governing intermediate sanctions are contained in Subpart O of parts 422 and 423. Sections 422.756 and 423.756 provide specific procedures for imposing intermediate sanctions and CMPs, and include provisions outlining the duration of the sanction.

Existing regulations at § 422.756(d)(3) and § 423.756(d)(3) incorporate the statutory standard by providing that the sanction remains in effect until we notify the sponsoring organization that we are satisfied that the basis for imposing the sanction has been corrected and is not likely to recur. Based on recent experience, it has been difficult at times for us to make the determination to lift a sanction. For example, when we impose an enrollment sanction on a sponsoring organization because it has failed to comply with enrollment and disenrollment requirements, it is very difficult for us to conclude that the sponsoring organization's enrollment deficiencies have been corrected and are not likely to recur when the organization is not permitted to enroll members. Difficulties also arise when the sponsoring organization attempts to fix deficiencies with highly technical internal business processes. In order to assist us in making the determination that the deficiencies have been corrected and are not likely to recur, we need to have greater flexibilities at our disposal.

We are proposing two changes to the regulation that provide additional flexibilities to assist us in making the determination to lift a sanction. First, we are proposing that we may require the sponsoring organization to hire an

independent auditor to provide us with additional information to determine if the deficiencies upon which the sanction was based have actually been corrected and are not likely to recur. The independent auditor would be hired by the sponsoring organization and work in accordance with our specifications in order to provide accurate and reliable information to CMS.

In making a determination to lift sanctions, we often must rely on either self-disclosed information from the sanctioned sponsoring organization, CMS data, some of which is also self-disclosed, or we must attempt to engage in a process to independently verify that the underlying deficiencies have been corrected and are not likely to recur. Given our experience with the nature and extent of some compliance deficiencies (for example, those caused by information technology system deficiencies or lack of adequate internal controls) and the need to obtain the level of skill and experience necessary to conduct an exhaustive audit and verification of the correction of these deficiencies, we have concluded that an independent auditor hired by the sponsoring organization would be beneficial for both the sponsoring organization and CMS. This proposal is consistent with our statutory authority which requires sponsoring organizations to provide information to us when we deem it is necessary and appropriate. An independent auditor, who is familiar with the processes of the sanctioned sponsoring organization, may be able to provide CMS with important information that we may use to help us make a more timely decision as to when to lift a sanction.

A similar approach is used by the HHS Office of Inspector General (OIG) in their Corporate Integrity Agreements and/or Self-Disclosure Protocol processes. The OIG often negotiates compliance obligations with health care providers and other entities as part of the settlement of Federal health care program investigations. A provider or entity consents to these obligations as part of the civil settlement and in exchange for the OIG's agreement not to seek an exclusion of that health care provider or entity from participation in Medicare, Medicaid, and other Federal health care programs. The typical terms of a comprehensive OIG corporate integrity agreement include the requirement for the provider to retain an independent review organization to provide independent validation and verification of adherence to Medicare requirements in relevant areas where

the provider has been found to be noncompliant.

We do not intend to require all sponsoring organizations that are under intermediate sanctions to hire an independent auditor because not all determinations will require the expertise of an independent auditor. However, there are situations when the expertise of an independent auditor will be helpful and in those cases, we are proposing we be afforded the discretion to require that an auditor be hired by the sponsoring organization. For example, an independent auditor who specializes in complex information technology systems and who has knowledge of how the systems interact with each other to be compliant with our requirements may be helpful in those instances where an organization with enrollment and disenrollment processing systems has been sanctioned. This is an example of a situation where we would require the sponsoring organization to hire an independent auditor in order to assist in making the determination that the deficiencies that formed the basis of the sanction have been corrected and are not likely to recur.

We are also considering an alternative proposal whereby instead of providing us with the authority to require sponsoring organizations to engage an independent auditor, we would grant sponsoring organizations the discretion to hire an independent auditor to evaluate the organization's compliance with our requirements. We would afford the results of the independent auditor's review some weight in our determination of whether the bases for the sanction have been corrected and are not likely to recur. We invite comments from sponsors and the industry about this alternative proposal and suggestions on other options we could implement to accomplish the desired outcome.

At this time we are proposing to add language to § 422.756 and § 423.756 that would allow us to require that a sponsoring organization hire an independent auditor to provide us with additional information to determine if the deficiencies that are the basis for a sanction have been corrected and are not likely to recur. Under either this proposal or our alternative proposal, the independent auditor would work in accordance with our specifications and must be willing to attest that a complete and full independent review has been performed.

Next, we are proposing that in instances where an enrollment and/or marketing suspension has been imposed, we may determine that it is appropriate to subject the sponsoring

organization to a "test period" whereby the organization or sponsor will, for a limited time, engage in marketing activities and/or accept enrollments in order to assist us in making a determination as to whether the bases for the sanctions have been corrected and are not likely to recur. The basis for this proposal is that we have found that there is often not a satisfactory way to determine if marketing and/or enrollment problems have been corrected while a sanction is in place and no such activities are permitted. Similarly, sponsoring organizations also have experienced challenges in demonstrating to us that these kinds of deficiencies have been corrected and are not likely to recur while they are under marketing and/or enrollment sanctions. In order to lift intermediate sanctions as expeditiously as possible when the sponsoring organization has corrected the deficiencies and to protect beneficiaries if the deficiencies have not been fully corrected, this proposed provision will permit us to assess whether the deficiencies upon which the sanction was made have been corrected and are not likely to recur by conducting a test of the organizations or sponsor's processes. The specific requirements for the marketing and/or enrollment "test period" will be determined by considering numerous factors, including but not limited to: the size of the organization, the specific deficiencies, and the timeframe in which the "test period" is conducted.

This provision will benefit sponsoring organizations, beneficiaries, and CMS. Sponsoring organizations will have an effective way to demonstrate that a sanction should be lifted. Beneficiaries will be protected because we will have sufficient evidence that deficiencies have been corrected prior to lifting sanctions and we will be assured that the bases for the sanctions have been corrected and are not likely to recur.

Therefore, we are proposing to add language to § 422.756 and § 423.756 that in instances where marketing or enrollment or both intermediate sanctions have been imposed, we may determine, in our sole discretion, that it is appropriate to require the sponsoring organization to market and/or to accept enrollments for a limited time in order to assist us in making a determination as to whether the deficiencies that are the bases for the intermediate sanctions have been corrected and are not likely to recur. Following this time period, if we determine the deficiencies have not been corrected or are likely to recur, the intermediate sanction will remain in effect until such time that we are assured the deficiencies have been

corrected and are not likely to recur. The sponsoring organization would have not had a right to a hearing to challenge our determination to keep the sanction in effect.

In addition to the above proposed changes to § 422.756 and § 423.756, we are proposing to delete the existing provisions at § 422.756(c) and § 423.756(c) which currently detail the three types of intermediate sanctions that may be imposed pursuant to our authority under sections 1857(g)(2)(B) through (C) and 1860D–12(b)(3)(E) of the Act. These provisions are duplicative of the list of sanctions at § 422.750(a) and § 423.750(a) and are unnecessary. Due to this deletion, we are proposing to redesignate paragraphs (d) through (f) in § 422.756 and § 423.756 as paragraphs (c) through (e), respectively.

10. Termination of Contracts Under Parts C and D (§ 422.510(a) and § 423.509(a))

Sections 1857(c)(2) and 1860D–12(b)(3)(B) of the Act permit CMS to terminate a sponsoring organization's contract if the sponsoring organization—

- Has failed substantially to carry out the contract;
 - Is carrying out the contract in a manner inconsistent with the efficient and effective administration of this part;
- or
- No longer substantially meets the applicable conditions of this part.

Existing regulations at § 422.510(a)(6) through (12) and § 423.509(a)(6) through (11) provide a number of bases (in addition to the statutory bases) upon which a contract may be terminated. This list does not include every reason for which we have the authority to terminate a contract. For example, the list does not explicitly include a provision that provides that a failure by the sponsoring organization to comply with enrollment and disenrollment regulations may be a basis for CMS termination. However, sponsoring organizations must follow enrollment and disenrollment regulations and a failure to comply with these regulations may be a basis for terminating the sponsoring organization's contract because it would have failed substantially to carry out the terms of its contract as required by the Act. We are concerned that by not specifically including each and every requirement on this enumerated list, organizations may be under the mistaken impression that we cannot take an action to terminate (or non-renew) a contract, or sanction an organization, for a failure to comply with a requirement(s) that is not

enumerated. Therefore, we are proposing to delete the enumerated bases for termination contained at § 422.510(a)(6) through (12) and § 423.509(a)(6) through (11). In addition, we are proposing to revise § 422.510(a) and § 423.509(a) to separate the language into two paragraphs. The first paragraph, (a)(1), will list the statutory bases for termination under sections 1857(c)(2) and 1860D–12(b)(3)(B) of the Act which state that we may at any time terminate a contract if we determine that the sponsoring organization has: (i) Failed substantially to carry out the contract; (ii) is carrying out the contract in a manner inconsistent with the efficient and effective administration of this part; or (iii) no longer substantially meets the applicable conditions of this part. The second paragraph, (a)(2), will clarify—(i) that a sponsoring organization's failure to comply with our regulations, (ii) failure to meet performance standards; and/or (iii) participation in false, fraudulent, or abusive activities, may constitute a basis for CMS to determine that the sponsoring organization meets the requirements for contract termination in accordance with paragraph (a)(1).

More specifically, we are proposing to add new language to § 422.510(a)(2)(i) and § 423.509(a)(2)(i) that failure to comply with any of the regulatory requirements contained in Parts 422 or 423 may constitute a basis for CMS to determine that the sponsoring organization meets the requirements for contract termination in accordance with paragraph (a)(1). This new provision is intended to clarify that compliance with all regulations is necessary to remain a contracting organization with CMS and if the sponsoring organization's failure to comply with the regulations supports one or more of the bases for termination in paragraph (a)(1), then we may terminate the contract.

We are also proposing to add new language to § 422.510(a)(2)(ii) and § 423.509(a)(2)(ii) that failure to meet our performance expectations in carrying out the Part C and Part D regulatory requirements may constitute a basis for us to determine that the sponsoring organization meets the requirements for contract termination in accordance with proposed paragraph (a)(1). This includes when we determine that a sponsoring organization is out of compliance with a Medicare requirement because our analysis of data related to that sponsoring organization's performance indicates it is an outlier relative to that of other organizations.

In some instances, we may use an outlier analysis to determine a sponsor's

performance relative to industry standards that were established by looking at the performance of all sponsors across the program, as described earlier in the preamble in our discussion of the development of our policies concerning the awarding, monitoring, and enforcement of Medicare contracts. This strategy is part of a larger strategy to oversee the program using a data driven, risk-based, transparent approach. This information is used to monitor plan sponsor compliance and make plan-specific and programmatic decisions. As reflected in the proposed regulations, in addition to using these data for program-wide evaluations and assessments, these performance standards will continue to be used to make assessments concerning compliance with our requirements and, when deemed appropriate, to take CMS contract actions, including contract termination and nonrenewal.

Finally, in our proposed language we are retaining the authority to terminate a sponsoring organization that has committed or participated in false, fraudulent, or abusive activities as currently stated in § 422.510(a)(4) and § 423.509(a)(4). However, we are proposing to redesignate current § 422.510(a)(4) and § 423.509(a)(4) as § 422.510(a)(2)(iii) and § 423.509(a)(2)(iii), respectively, as such failures may also constitute a basis for us to determine that the sponsoring organization meets the requirements for contract termination in accordance with the proposed revisions to paragraph (a)(1).

In addition, we are proposing additional amended language to this regulation. The existing regulations permit us to terminate a contract only when we determine that a sponsoring organization's fraudulent activities concern the Medicare program. We believe that we should not be contracting with MA organizations and Part D sponsors who commit or participate in fraudulent activities related to any governmental health care programs. Therefore, we are proposing to amend this regulation to include false, fraudulent, or abusive activities affecting Medicaid, or other State or Federal health care programs.

In addition, existing regulations that govern termination at § 422.510(a)(5) and § 423.509(a)(5) provide that we may terminate a contract if the sponsoring organization experiences financial difficulties so severe that its ability to make necessary health services available is impaired to the point of posing an imminent and serious risk to the health of its enrollees, or otherwise fails to make services available to the extent

that such a risk to health exists. This language incorporates the Secretary's authority under sections 1857(h)(2) and 1860D–12(b)(3)(F) of the Act to take an immediate termination if it is determined that a delay in termination, in order to comply with the CAP and appeal termination procedures, would pose an imminent and serious risk to the health of the individuals enrolled. We are proposing changes elsewhere in these regulations to our provisions governing expedited terminations. Therefore, we are proposing to delete the regulatory text contained at § 422.510(a)(5) and § 423.509(a)(5). Recognizing that it is not possible to enumerate every reason for which we have the authority to terminate a contract, we believe we have reached a good balance between providing sufficient regulatory detail and preserving administrative flexibility. When regulatory provisions require further clarification, we plan to further define through subregulatory guidance how we would operationalize these provisions. We have historically used our manual chapters, reporting requirements, and marketing guidelines to indicate how we measure compliance with our performance requirements and what we consider acceptable practice. We solicit comment on whether these regulatory provisions provide sufficient clarity. If not, we solicit comment on whether clarification should be provided through regulation or subregulatory guidance, such as the annual Call Letter or our Manual.

11. Request for Hearing Under Parts C and D (§ 422.662 and § 423.651)

Sections 1857(c) and 1860D–12 of the Act permit us to terminate contracts with sponsoring organizations. Current regulations at § 422.662(a) and § 423.651(a) governing the hearing procedures require sponsoring organizations to file a request for a hearing on contract determinations with the Hearing Officer and to also file it with "any CMS office." This procedure is ineffective and inefficient because it is likely to result in a request for hearing not being received by the appropriate officials within CMS. Consequently, we are proposing a modification in the language contained at § 422.662(a) and § 423.651(a) to state that the sponsoring organization must file the request for a hearing in accordance with the requirements specified in the notice of the contract determination or intermediate sanction, thus ensuring that the proper officials within CMS receive the request and can act upon the request in a timely manner.

We are also making a conforming change at § 422.662(b) and § 423.651(b) which govern the timeframes for filing the request for hearing to provide that the request must be filed within 15 calendar days after receipt of the notice (versus the existing language which states 15 calendar days from the “date CMS notifies” the sponsoring organization of its determination). This change is to ensure consistency with the way deadlines are described in other regulatory provisions of parts 422 and 423 governing contract determinations or the imposition of intermediate sanctions (including related appeals processes).

12. Burden of Proof, Standard of Proof, Standards of Review, and Conduct of Hearing (§ 422.660, § 423.650, § 422.676 and § 423.658)

Under the existing regulations at § 422.660(b), and § 423.650(b), when appealing a contract determination or an intermediate sanction, the sponsoring organization bears the burden of proof to demonstrate that it was in “substantial compliance” with our requirements on the “earliest of” following three dates:

- The date of the notice of contract determination or intermediate sanction.
- The date of the most recent onsite audit.
- The date of the alleged breach of the current contract or past substantial noncompliance as determined by CMS.

In practice, these existing standards of review (“substantial compliance” and “earliest of test”) have led to confusion among parties to the hearing and have been difficult for the Hearing Officer to apply. We have come to realize that the existing “substantial compliance” standard of review articulated at § 422.660(b), and § 423.650(b) does not reflect the nuances of the different legal standards provided in the Act for making contract determinations and imposing intermediate sanctions. For example, sections 1857(c)(2)(B) and 1860D–12(b)(3)(F) of the Act provide that the Secretary may terminate a contract if the Secretary finds that the sponsoring organization “has failed substantially to carry out the contract, is carrying out the contract in a manner inconsistent with the efficient and effective administration of this part, or no longer substantially meets the applicable conditions of this part.” Similarly, there is no reference to a substantial compliance standard in the bases available to CMS for imposing intermediate sanctions. Based on these nuances, we have determined that the application of the substantial compliance standard of review to all

appeals is unnecessarily confusing and may have led to unintended consequences in that it may have distorted review of the applicable statutory and regulatory requirements. Accordingly, we are proposing to delete “substantial compliance” as a standard of review.

In addition to the preceding, the “earliest of” test does not accurately reflect how and when we make our determinations for different contract actions or intermediate sanctions. For example, when making a determination as to whether or not we should enter into a contract with an applicant, we review all of the information that the applicant provides and decides whether it meets our standards according to § 422.501 and § 422.502 or § 423.502 and § 423.503. If the applicant does not meet those standards, then we will deny the application. During a hearing, it would be inappropriate for the applicant to insist that its application should be approved because it corrected its deficiencies after we issued a denial of the application. The “earliest of” test may create this mistaken impression because it provides that during a hearing the applicant must demonstrate that it was in “substantial compliance” with our requirements on the “earliest of” one of three dates. This creates confusion and imposes an unworkable time period for the applicant or sponsoring organization to demonstrate that it has met CMS standards. Therefore, we are also proposing to delete the existing regulations which provide for an “earliest of” test.

Finally, though the existing regulations explicitly state that the sponsoring organization bears the burden of proof, it does not provide the standard of proof that is to be applied by the hearing officer. We believe that the sponsoring organization bearing the burden of proof is appropriate since the purpose of the hearing is to provide the sponsoring organization an opportunity to appeal and dispute our contract determination or imposition of intermediate sanction. Therefore, we believe that no change is necessary concerning the burden of proof. In order, however, to more clearly articulate the standard of proof and standards of review we are proposing the following changes to our regulations.

First, we are clarifying the standard of proof that we believe applies to these appeals proceedings. It has been our experience that the hearing officer does appropriately use the preponderance of evidence standard when weighing the evidence at a hearing for an appeal of a CMS contract determination or

imposition of intermediate sanction. We believe, however, that it is important to explicitly state the standard of proof so as to provide as much clarity and consistency as possible for the Hearing Officers and the parties to a hearing. In addition, the preponderance of the evidence standard is consistent with the standard of proof used in Subparts T to Parts 422 and 423 which governs appeal proceedings for civil money penalties.

Second, we are addressing the use of a proper standard of review. The proposed standard of review that we believe applies to these appeal procedures is dependent on the type of contract determination or intermediate sanction. Our proposed revisions make explicit which standard of review is to be applied by the Hearing Officer to the three types of contract determinations identified at § 422.641(a) and § 423.641(a) and to intermediate sanctions identified at § 422.750 and § 423.750 by noting the different requirements for each type of action. Specifically, the proposed regulation clarifies that the standards of review are different for determinations involving Part C or D contract application qualifications, those involving the termination or non-renewal of a sponsoring organization’s contract, and those involving the imposition of intermediate sanctions. These separate and distinct standards of review are intended to reflect the inherent differences in the processes and standards we use to make each type of determination.

Therefore, we are proposing to delete the existing language contained at § 422.660(b) and § 423.650(b) and replace it with language which provides that the applicant or the sponsoring organization has the burden of proving by a preponderance of the evidence that our determination was inconsistent with the requirements of the applicable part. We specify that these requirements are § 422.501 and § 422.502 that governs the processes and standards for applicants for the MA program, § 423.502 and § 423.503 for applicants for the Part D program, § 422.506 or § 422.510 for MA contract determinations, § 423.507 or § 423.509 for Part D contract determinations, and § 422.752 or § 423.752 for intermediate sanctions.

Additionally, we propose to modify § 422.660(c) and § 423.660(c), which currently specify that the notice of any decision favorable to a Part C or D applicants appealing a determination that it is not qualified to enter into a contract with us must be issued by July 15th for the contract in question to be effective on January 1st of the following year. We propose changing the July 15th

deadline to September 1st. Over the past 4 years, we have found the July 15th deadline to be an unreasonable timeframe within which to complete the hearing process afforded denied applicants pursuant to Subpart N of Parts 422 and 423. September 1st allows sufficient time for an applicant to receive a decision issued by the CMS Hearing Officer on the status of its application and for us to contract with the applicant should the applicant receive a favorable decision.

Accordingly, we are also proposing to make the following conforming changes to § 422.660 and § 423.650.

- Revise the section headings for § 422.660 and § 423.650 to read “Right to a hearing, burden of proof, standard of proof, and standards of review” in order to conform with the section headings to our proposed changes.

- Add paragraph headings. We believe that these additions would improve the structure and readability of the proposed regulatory text.

- Correct the references in § 422.660(a)(1) and § 423.650(a)(1). Sections 422.660(a)(1) and 423.650(a)(1) currently state that a contract applicant that has been determined to be unqualified to enter into a contract with CMS under § 422.501 and § 423.503 respectively, is entitled to a hearing. The correct citations for the sections that we use when making a determination as to whether to enter into a contract with an applicant are § 422.501 and § 422.502 for Part C contracts and § 423.502 and § 423.503 for Part D contracts. Therefore, we are proposing to accurately reflect these references in the regulations by making a technical change which incorporates the appropriate and necessary citations by adding the reference § 422.502 to § 422.660(a)(1), and by adding the reference § 423.502 to § 423.650(a)(1).

- Make technical changes in § 422.660(a) and § 423.650(a). In paragraphs (a)(1) through (a)(4) of these sections, we are proposing to revise the terminology preceding the cross-reference (that is, change “pursuant to” to “in accordance with” or “under”), adding a section symbol before the section number, and completing the cross-reference by adding the phrase “of this part” after the section number.

Finally, we are also proposing to modify the existing regulations at § 422.676(d) and § 423.658(d) governing the conduct of the hearing. We are proposing to revise the language contained in § 422.676(d) and § 423.658(d) to provide that, consistent with the burden of proof, during the hearing the sponsoring organization bears the burden of being the first to

present its argument to the Hearing Officer according to any briefing schedule determined by the Hearing Officer. We believe that requiring the sponsoring organization to present its argument to the Hearing Officer first is appropriate since the basis for our determination is detailed in the notice of determination that is sent to the sponsoring organization. Since the purpose of the sponsoring organization’s appeal is to dispute our determination it seems appropriate that the sponsoring organization should first be required to present its argument as to why it believes the determination is incorrect or otherwise not supported prior to CMS’ putting on its case in support of its contract or intermediate sanction determination.

13. Expedited Contract Terminations Procedures (§ 422.510, § 423.509, § 422.664, § 423.652, § 422.644, and § 423.642) Under Parts C and D

Sections 1857(h)(2) and 1860D–12(b)(3)(F) of the Act provide the procedures requiring reasonable notice and opportunity to develop and implement a CAP and for a hearing shall not apply prior to termination if the Secretary determines that a delay in termination, resulting from compliance with these procedures would pose an imminent and serious risk to the health of individuals enrolled with the sponsoring organization. These kinds of terminations are referred to as “expedited terminations” under current regulations.

Sections 422.510(a)(4) and (5), and § 423.509(a)(4) and (5) currently provide two of these bases for expedited terminations. Under § 422.510(a)(4) and § 423.509(a)(4), we may terminate a contract when there is credible evidence that the sponsoring organization committed or participated in false, fraudulent, or abusive activities affecting the Medicare program. Under § 422.510(a)(5) and § 423.509(a)(5), we may terminate a contract when the sponsoring organization experiences financial difficulties so severe that its ability to make necessary health services available is impaired “to the point of posing an imminent and serious risk to the health of its enrollees or otherwise fails to make services available to the extent that such a risk to health exists”, thereby incorporating the expedited termination statutory language.

Termination procedures at § 422.510(c)(2) and § 423.509(c)(2) provide that if a contract is terminated under § 422.510(a)(4) or (a)(5), and § 423.509(a)(4) or (a)(5), the sponsoring organization will not have the opportunity to submit a CAP prior to

termination. Our notice of termination procedures also provide at § 422.510(b)(2)(i) and § 423.509(b)(2)(i) that, if a contract is terminated under § 422.510(a)(4) or (a)(5) and § 423.509(a)(4) or (a)(5), we will notify the sponsoring organization that its contract will be terminated on a date specified by CMS. Appeal procedures at § 422.664(b)(2) and § 423.652(b)(2) currently provide that a contract terminated under either of these bases will be terminated on the date specified by CMS and will not be postponed if a hearing is requested.

These current regulations governing expedited terminations do not adequately reflect the scope of the Secretary’s authority under section 1857(h)(2) and 1860D–12(b)(3)(F) of the Act. The Act does not limit the Secretary’s authority to effectuate expedited terminations solely based on the circumstances prescribed in § 422.510(a)(4) or (a)(5), and § 423.509(a)(4) or (a)(5) and therefore, these regulations are unduly limiting. If compliance with the CAP provisions and hearing procedures prior to termination would pose an imminent and serious risk to the health of individuals enrolled with the sponsoring organization, the Act permits us to terminate a contract without providing a right to a CAP or hearing prior to termination. While the current regulations provide several instances where such a determination would be appropriate, these are not the only instances where such a determination would need to be made to protect beneficiaries from imminent and serious risk to their health.

Therefore, we are proposing to delete the references to § 422.510(a)(4) or (a)(5) and § 423.509(a)(4) or (a)(5) as contained in the termination (§ 422.510(b)(2)(i), § 423.509(b)(2)(i), § 422.510(c)(2) and § 423.509(c)(2)) and in the appeal procedures (§ 422.664(b)(2) and § 423.652(b)(2)). More specifically, we are proposing to amend the termination procedures language of § 422.510(b)(2)(i) and § 423.509(b)(2)(i) to clarify that for terminations based on violations prescribed in § 422.510(a) and § 423.509(a), if we determine that a delay in termination, resulting from compliance with CAP and hearing procedures prior to termination, would pose an imminent and serious risk to the health of the individuals enrolled with the sponsoring organization, the effective date of the termination will be specified, in writing by CMS. In addition, we are proposing to amend the termination procedures language at § 422.510(c)(2) and § 423.509(c)(2) to clarify that if we determine that a delay

in termination, resulting from compliance with the CAP procedures, would pose an imminent and serious risk to the health of the individuals enrolled with the MA organization or Part D sponsor, the MA organization or Part D sponsor will not be provided with an opportunity to develop and implement a CAP prior to termination. Lastly, we are proposing to amend the appeals procedures language at § 422.664(b)(2) and § 423.652(b)(2) to state that if we determine that a delay in termination, resulting from compliance with the notice and opportunity for hearing procedures, prior to termination, would pose an imminent and serious risk to the health of individuals enrolled with the MA organization or Part D sponsor, the date of termination will not be postponed if the MA organization or Part D sponsor requests a hearing.

It is important to note that our proposal to delete the references to § 422.510(a)(4) or (a)(5), and § 423.509(a)(4) or (a)(5) contained in the existing termination and appeal procedures should not be interpreted in any way to limit our ability under our statutory authority to expedite a termination when we determine that a sponsoring organization is experiencing severe financial difficulty, otherwise fails to make services available to the extent that such a risk to the health exists or when there is credible evidence that a sponsoring organization committed or participated in false, fraudulent, or abusive activities.

We are also making conforming changes (to ensure consistency of the proposed regulations) to the termination notice procedures contained in § 422.510(b) and § 423.509(b) and notice of contract determinations contained in § 422.644(c) and § 423.642(c) which reference the expedited termination bases. In § 422.510(b) and § 423.509(b), we are deleting the references to § 422.510(a)(4) or (a)(5), and § 423.509(a)(4) or (a)(5). In § 422.644(c) and § 423.642(c), we are deleting the references to § 422.510(a)(4) or (a)(5), and § 423.509(a)(4) or (a)(5) and replacing the language with the proposed language contained in § 422.510(b)(2)(i) and § 423.509(b)(2)(i).

14. Time and Place of Hearing Under Parts C and D (§ 422.670 and § 423.655)

Sections 1857(h)(1)(b) and 1860D–12(b)(3)(F) of the Act provide the procedures requiring reasonable notice and opportunity for hearing when we terminate a sponsoring organization's contract. Current regulations at § 422.670(b) and § 423.655(b) provide the Hearing Officer may, on his or her

own motion, or at the request of party, change the time and place for the hearing and may adjourn or postpone the hearing. Based on our experience with this process, we believe that both sponsoring organizations and we may need additional time to prepare for a hearing. Therefore, we are proposing to add language to § 422.670(b) and § 423.655(b) to state the sponsoring organization or we may request that the hearing date be postponed by filing a written request no later than 5 calendar days prior to the scheduled hearing, when either the sponsoring organization or CMS requests an extension, the Hearing Officer will provide a one-time 15 calendar day postponement, and additional postponements may be granted at the discretion of the Hearing Officer.

In addition, current regulations at § 422.670(a) and § 423.655(a) require that the CMS Hearing Officer schedule a hearing to review a contract determination or the imposition of an intermediate sanction within 30 calendar days from the "receipt of request for the hearing." We are proposing to change the language at § 422.670(a) and § 423.655(a) to provide that the CMS Hearing Officer schedule a hearing to review a contract determination or the imposition of an intermediate sanction within 30 calendar days after the "receipt of the request for the hearing." This change is to ensure consistency with the way deadlines are described in other regulatory provisions of parts 422 and 423 governing contract determinations or the imposition of intermediate sanctions (including related appeals processes).

15. Discovery Under Parts C and D (§ 422.682 and § 423.661)

Sections 1857(h)(1)(b) and 1860D–12(b)(3)(F) of the Act provide the procedures requiring reasonable notice and opportunity for hearing when we terminate a sponsoring organization's contract. The statute does not require a formal discovery process for CMS appeal procedures. In the December 5, 2007 final rule, we provided in § 422.682 and § 423.661 for a formal discovery process prior to hearing. However, based on our experience since the promulgation of this rule, we do not now believe a formal discovery process is necessary or appropriate for these kinds of proceedings. In addition, the existing timeframe in which the hearing normally must take place, 30 calendar days after request for a hearing, does not easily accommodate a formal discovery process.

Therefore, we are proposing to delete the formal discovery process contained in § 422.682 and § 423.661. Simultaneously, we need to ensure that both parties receive witness lists and relevant documents with enough time prior to the hearing while at the same time ensuring the hearing is conducted in a timely and orderly fashion.

Therefore, we are proposing to amend the regulations at § 422.682 and § 423.661. First, we propose to modify the existing regulations to change the titles of § 422.682 and § 423.661 from "Discovery" to "Witnesses and Documents" to reflect the changes made. Second, under this newly titled section, we are proposing to substitute new language which requires that witness lists and documents must be identified and exchanged at least 5 calendar days prior to the scheduled hearing. We believe this change more appropriately reflects what is necessary to meet the evidentiary needs of the parties by providing the parties with the appropriate amount of information in advance of the hearing to present their evidence and counter arguments.

Additionally, existing regulations at § 422.670(a)(2) and § 423.655(a)(2) currently provide that the Hearing Officer will notify the parties of the ability to conduct formal discovery. Because we are proposing to delete the formal discovery processes in § 422.682 and § 423.661, we are proposing to make a conforming change by deleting § 422.670(a)(2) and § 423.655(a)(2).

16. Review by the Administrator Under Parts C and D (§ 422.692(a) and § 423.666(a))

Sections 1857(h)(1)(b) and 1860D–12(b)(3)(F) of the Act provide the procedures requiring reasonable notice and opportunity for hearing when we terminate a sponsoring organization's contract. Our current regulations at § 422.692 and § 423.666 provide for a sponsoring organization to request review by the CMS Administrator of a hearing decision. These existing regulations provide that a sponsoring organization may request review by the Administrator within 15 calendar days of "receiving the hearing decision."

We are proposing to revise the language at § 422.692(a) and § 423.666(a) to provide that the sponsoring organization may request review by the Administrator within 15 calendar days after "receipt of the hearing decision." In addition, we are proposing to change the language at § 422.692(c) and § 423.666(c) governing the notification of Administrator determination to state that the Administrator must notify both parties

of his or her determination regarding review of the hearing decision within 30 calendar days after “receipt of the request for review” (versus the existing language which provides within 30 calendar days of “receiving the request for review”). These changes ensure consistency with the way deadlines are described in other regulatory provisions of Parts 422 and 423 governing contract determinations or the imposition of intermediate sanctions (including related appeals processes).

17. Reopening of an Initial Contract Determination or Decision of a Hearing Officer or the Administrator Under Parts C and D (§ 422.696 and § 423.668)

Sections 1857(h)(1)(b) and 1860D–12(b)(3)(F) of the Act provide the procedures requiring reasonable notice and opportunity for hearing when we terminate a sponsoring organization’s contract. Our current regulations at § 422.696 and § 423.668 govern the reopening of an initial contract determination or decision of a Hearing Officer or the Administrator. More specifically, existing regulations at § 422.696(a) and § 423.668(a) state that we may reopen and revise an “initial determination” upon our own motion. The term “initial determination” is not used elsewhere in Subpart N (Contract determinations and Appeals). Therefore, we are proposing to revise these regulations by replacing the language “initial determination” with “contract determination” in the section headings of § 422.696 and § 423.668 and in the text of § 422.696(a) and § 423.668(a).

18. Prohibition of MA and Part D Applications for 2 Years After a Mutual Termination (§ 422.503(b)(6) and § 423.504(b)(5))

The regulations in § 422.503(b)(6) and § 423.504(b)(5) currently provide that MA organizations and Part D sponsors that nonrenew contracts with CMS are considered unqualified to recontract with us for a period of 2 years, unless we identify circumstances that warrant special consideration. This is consistent with § 422.506(a)(4) and § 423.507(a)(3), which describe contract nonrenewal requirements and procedures. We interpret these provisions to apply to MA organizations and Part D sponsors that nonrenew all of their contracts with us in a given area for a given line of business (MA or Part D), thereby severing their contractual relationship with the Agency across all of their MA, Part D, or both lines of business in the area. We have not interpreted this provision to apply to an organization that, for instance, holds many MA contracts in an area but chooses to

nonrenew fewer than all of those contracts.

In practice, a voluntary nonrenewal of a contract by a Part D sponsor or MA organization is not dissimilar from an organization requesting and being granted a mutual termination of their contract under § 422.503 and § 423.508. The primary difference between the two events is often timing, whereby a nonrenewal request to take effect at the end of the current contract year must be received by us on or before the first Monday in June (the bid deadline), as specified in § 423.507(a)(2)(i) and § 422.506(a)(2)(i). Once an organization submits a bid, it can no longer voluntarily nonrenew its contract for the following year. Rather, the Part D sponsor or MA organization must request a mutual contract termination. The later in the year the organization requests such a mutual termination for the following contract year, the more disruptive and difficult the process becomes. Particularly, once the organization completes all of its contract renewal obligations, such as signing a new bid attestation and a contract with CMS, where applicable, we begin including the new plan offerings under the contract on our Web site and in print materials to inform beneficiaries about the opportunity to enroll in those plan offerings for the upcoming contract year. To request a mutual contract termination late in the year once such information has become publicly available, marketed to beneficiaries, and beneficiaries have been given the opportunity to enroll is to create significant disruption for us and beneficiaries. Similarly, even greater disruption results from mutual terminations requested to take effect during the course of a contract year.

Circumstances are sometimes such that the requesting MA organization or Part D sponsor is requesting the mutual termination because it realizes it would be significantly out of compliance with one or more program requirements should it keep the contract in place. Therefore, it is sometimes in the organization’s and our interest to execute the mutual termination. Nevertheless, the disruption is significant and completely the responsibility of the sponsor. Yet, currently the regulations are silent on whether the MA organization or Part D sponsor would be qualified to enter into new contracts with CMS in future years. We believe that a termination by mutual consent, which involves a termination by an MA organization or a Part D sponsor as well as by CMS, should be considered a termination of a contract for purposes of the 2-year ban on

entering into new contracts under section 1857(c)(4)(A) of the Act, which is incorporated for Part D under section 1860D–12(b)(3)(B) of the Act.

For these reasons, we are proposing that as a condition of the consent to a mutual termination, we will prohibit the MA organization or Part D sponsor from applying for new contracts or service area expansions for a period of 2 years, absent circumstances that warrant special consideration as provided under section 1857(c)(4)(A) of the Act. Such language would be incorporated into the mutual termination consent agreement to be signed by both parties.

Therefore, we are proposing to modify § 423.508 by adding paragraph (e), which states that as a condition of the consent to a mutual termination, we will require as a provision of the termination agreement language prohibiting the Part D sponsor from applying for new contracts or service area expansions for a period of 2 years, absent circumstances warranting special consideration. Similarly, in § 423.504(b), we propose to add a new paragraph (b)(6) stating that organizations may be qualified to apply for new contracts to the extent that they have not terminated a contract by mutual consent under which, as a condition of the consent, the Part D sponsor agreed that it was not eligible to apply for new contracts or service area expansions for a period of 2 years per § 423.508(e). To accomplish these changes, we propose to redesignate the current § 423.504(b)(6) to § 423.504(b)(7).

We propose to make the same modification to the MA regulations. Specifically, we are proposing to modify § 422.508 by adding paragraph (c), which states that as a condition of the consent to a mutual termination, we will require as a provision of the termination agreement language prohibiting the MA organization from applying for new contracts or service area expansions for a period of 2 years, absent circumstances warranting special consideration. Similarly, in section § 422.503(b), we propose to add a new paragraph (b)(7), stating that organizations may be qualified to apply for new contracts to the extent that they have not terminated a contract by mutual consent under which, as a condition of the consent, the MA organization agreed that it was not eligible to apply for new contracts or service area expansions for a period of 2 years per § 422.508(c).

B. Changes To Strengthen Beneficiary Protections

This section includes provisions aimed at strengthening beneficiary protections under Parts C and D. Under Part D, we address proposals in the area of eligibility and enrollment policy, transition period requirements, coordination of benefits policy, retroactive claims adjustment reimbursements and recoveries, and use of standardized technology. We also propose to revise Part D rules regarding timeframes and responsibility for making redeterminations.

Under Part C, we propose to revise our rules to—

- Authorize us to annually establish an overall annual cap on member cost sharing;
- Prohibit PPO, PFFS, and MSA plans from using compliance with voluntary prior notification procedures in determining cost-sharing amounts;
- Establish new requirements for organization determinations; and
- Offer two definitional revisions.

In the area of Parts C and D marketing, we continue to monitor plans that use independent agents and brokers to ensure sponsoring organizations adhere to CMS requirements. In this rule, we

solicit comments on options aimed at further protecting beneficiaries in this area. We also propose to strengthen our marketing requirements, distinguishing marketing materials from enrollee communications materials and mandating the use of standardized marketing material language and format to ensure clarity and accuracy among plan documents. We also clarify notice requirements, and propose that sponsoring organizations disclose information concerning the organization’s performance and compliance deficiencies to enable beneficiaries to make informed choices. This information is detailed in Table 2.

TABLE 2—PROVISIONS TO STRENGTHEN BENEFICIARY PROTECTIONS

Provision	Part 422		Part 423	
	Subpart	Section	Subpart	Section
Broker & Agent Requirements under Parts C and D	N/A	N/A	N/A	N/A.
Beneficiary Communications Materials under Parts C and D.	Subpart V	§ 422.2260, § 422.2262	Subpart V	§ 423.2260, § 423.2262.
Required Use of Standardized Model Materials under Parts C and D.	Subpart V	§ 422.2262	Subpart V	§ 423.2262.
Extend the mandatory minimum grace-period for failure to pay premiums.	Subpart B	§ 422.74	Subpart B	§ 423.44.
Maximum allowable out-of-pocket cost amount for Medicare Parts A and B services.	Subpart C	§ 422.100	N/A	N/A.
Maximum allowable cost sharing amount for Medicare Parts A and B services and prescription drugs.	Subpart C	§ 422.100	Subpart C	§ 423.104
Prohibition on prior notification by PPO, PFFS, and MSA plans.	Subpart A	§ 422.2, § 422.4, § 422.105(b).	N/A	N/A
Requirements for LIS eligibility: Expand the deeming period for LIS-eligible beneficiaries to cover at least 13 months.	N/A	N/A	Subpart P	§ 422.773(c)(2).
Expand auto-enrollment rules to entire LIS-eligible population.	N/A	N/A	Subpart B	§ 423.34
Special Enrollment Period (SEP) Policies	N/A	N/A	Subpart B	§ 423.38.
Transition Process	N/A	N/A	Subpart C	§ 423.120(b)(3).
Sponsor responsibility for retroactive claims adjustment reimbursements and recoveries.	N/A	N/A	Subpart J	§ 423.464.
Time Limits for Coordination of Benefits	N/A	N/A	Subpart J	§ 423.466.
Pharmacy use of Standard Technology (ID cards) under Part D.	N/A	N/A	Subpart C	§ 423.120.
Allow members in stand-alone Part D plans to be temporarily out of area for up to 12 months.	N/A	N/A	Subpart B	§ 423.44.
Prohibit mass SPAP reenrollments during plan year	N/A	N/A	Subpart J	§ 423.464(e).
Non-Renewal Public Notice 60-day non-renewal beneficiary notification requirement.	Subpart K	§ 422.506	Subpart K	§ 423.507.
Notice of Alternative Medicare Plans	Subpart K	§ 422.5(a)(2)(ii)	Subpart K	§ 423.507(2)(ii).
Timeframes and Responsibility for making Redeterminations under Part D.	N/A	N/A	Subpart M	§ 423.590.
Requirements for Requesting Organization Determinations.	Subpart M	§ 422.568	N/A	N/A.
Organization Determinations under Parts C	Subpart M	§ 422.566 & § 422.568	N/A	N/A.
Refine/clarify definitions related to authorized representatives.	Subpart M	§ 422.561, § 422.574 & § 422.624.	N/A	N/A.
Sponsors may be required to disclose to enrollees compliance and performance deficiencies.	Subpart C	§ 422.111(g)	Subpart C	§ 423.128(f).
Revise definition of “service area” to exclude facilities in which individuals are incarcerated.	Subpart A	§ 422.2	N/A	N/A.

1. Broker and Agent Requirements Under Parts C and D

Prior to January 1, 2006, beneficiaries could enroll in MA plans (then called

Medicare+Choice plans) at any time throughout the year, effective the first day of the next month. Under those circumstances, most MA plans were able to employ a full-time sales force.

Effective January 1, 2006, enrollment in MA plans and Part D prescription drug plans (PDPs) was limited to an annual coordinated election period in the fall, and in the case of MA plans only, the

open enrollment period during the first 3 months of the year. As a result, maintaining a full-time, year-round sales force became untenable for many organizations, leading to increasing reliance on independent agents and brokers to educate beneficiaries about their Medicare health care options and enroll them in their products.

In 2008, the Congress enacted the Medicare Improvements for Patients and Providers Act (Pub. L. 110–275) (MIPPA). In order to address concerns raised by reports of significant agent and broker misconduct in the market place, section 103 of MIPPA placed certain restrictions and limits on the marketing of MA plans and PDPs. Our objective in implementing the marketing requirements included in the MIPPA was to ensure that agent and broker compensation would not create financial incentives for agents and brokers to enroll Medicare beneficiaries in particular MA plans or PDPs based on considerations other than the best interests of the beneficiary.

In the September 18, 2008 **Federal Register**, we published an interim final rule with comment period (73 FR 54226) implementing the MIPPA compensation provisions. In the November 14, 2008 **Federal Register**, we published the Medicare Advantage & Prescription Drug Programs: Clarification of Compensation Plans interim final rule with comment period (73 FR 67406), which clarified and modified the September 18, 2008 rule in part because we believed that plans were misinterpreting certain provisions of the September 18, 2008 interim final rule. Because so little time has passed since the publication of these rules, we believe it is too soon to fully evaluate whether these changes involving agent compensation have achieved the MIPPA's goal of creating incentives for agents and brokers to assist beneficiaries with selecting plans based on their health care needs rather than on agent or broker financial interests.

We recognize the important role that agents and brokers play in assisting beneficiaries with accessing and understanding plan information, making informed choices, and enrolling them in Medicare health plans. However, we remain concerned about the inherent financial incentives independent agents and brokers have when selling Medicare products. For this reason, we are continuing to explore the most effective means of providing Medicare health plan and drug plan information and enrollment assistance in order to ensure that beneficiaries select the plan that best meets their needs, including whether additional changes are needed

in the requirements related to plan sponsors' use of agents and brokers.

Our overarching objective is that with any potential further limitations on independent agent and broker activity beneficiaries will continue to have the assistance they need to make health care choices best suited to their needs. We provide a number of tools, both through our print publications and our online resources (Medicare Options Compare, MPDPF, and Online Enrollment Center) to assist beneficiaries with their health care decisions, and we continuously seek to improve these tools. We are exploring whether State Health Insurance Assistance Programs (SHIPs) have the capacity to serve significantly more Medicare beneficiaries. We also are considering limiting the use of independent agents and brokers by MA organizations to certain times of the year, specifically, the open enrollment period (OEP) and annual enrollment period (AEP), or to selected groups of beneficiaries. Limiting the use of independent agents and brokers to the OEP and AEP or to a subset of beneficiaries would allow us to better focus our monitoring efforts throughout the year, while still recognizing the role independent agents and brokers play in assisting beneficiaries with obtaining and evaluating plan information (including year to year plan benefit changes), making informed choices, and enrolling in Medicare health plans.

While we are not proposing any changes at this time, we are seeking comments on the approaches discussed in this section, as well as other potential solutions to ensure that beneficiaries receive adequate assistance in understanding their choices and with enrollment, including potential alternative roles for agents and brokers. Any changes resulting from comments to this section will be implemented through future notice and comment rulemaking.

2. Beneficiary Communications Materials Under Parts C and D (§ 422.2260, § 422.2262, § 423.2260, and § 423.2262)

Section 1851(h) of the Act, which is made applicable to Part D in section 1860D–1(b)(1)(vi) of the Act, established requirements regarding the review and approval of marketing materials by MA organizations and PDP sponsors. Sections 422.2260 and 423.2260 of the regulations define marketing materials as informational materials targeted to Medicare beneficiaries which may include the following:

- General audience materials such as—
 - ++ General circulation brochures;

- ++ Newspapers;
- ++ Magazines;
- ++ Television;
- ++ Radio;
- ++ Billboards;
- ++ Yellow pages; or
- ++ The Internet.
- Marketing representative materials such as scripts or outlines for telemarketing or other presentations.
- Presentation materials such as slides and charts.
- Promotional materials such as brochures or leaflets, including materials for circulation by third parties (for example, physicians or other providers);
- Membership communication materials such as—
 - ++ Membership rules;
 - ++ Subscriber agreements;
 - ++ Member handbooks; and
 - ++ Wallet card instructions to enrollees.
- Letters to members about—
 - ++ Contractual changes;
 - ++ Changes in providers;
 - ++ Premiums;
 - ++ Benefits, plan procedures, and membership; or
 - ++ Claims processing activities.

Sections 422.2260, 422.2262, 423.2260, and 423.2262 codify requirements regarding CMS review and approval of marketing materials. Given a number of years of experience in implementing these processes under both the Part C and Part D programs, we have found that our definition of the term “marketing materials” is so broad as to encompass plan notification materials that are often either situational materials or beneficiary specific customized communications. As these materials are considered marketing materials, they are subject to our rules regarding review, distribution, and approval in § 422.2262 and § 423.2262. However, we have found that CMS Regional Office review and approval procedures for situational marketing materials should follow a separate review process determined by CMS. Materials that are beneficiary specific letters are not considered to be marketing materials such as—

- Part D explanations of benefits (EOBs);
- Notifications about claims processing changes or errors; and
- Other one-time or situational, beneficiary specific letters to current enrollees.

Therefore, we propose to revise § 422.2260 and § 423.2260 to exclude materials about claims processing activities from the definition of marketing materials. We also propose to add a definition of current enrollee

communications materials not to be considered marketing materials encompassing information targeted to situational or beneficiary-specific circumstances, including claims processing issues and other one-time communications about operations. In addition, we propose to revise § 422.2262 and § 423.2262 to specify that, while current enrollee communications are not subject to the statutory requirement that applies to marketing materials (that is, that they be submitted to CMS for review prior to use), we retain the right to review them, and their use could be disapproved by CMS, or disapproved unless modifications are made. We believe these changes will streamline the review and approval of beneficiary communication notices to current members.

3. Required Use of Standardized Model Materials Under Parts C and D (§ 422.2262 and § 423.2262)

Section 1851(h) of the Act establishes standards for review and approval of marketing materials. Section 1860D–1(B)(1)(vi) of the Act requires CMS to use rules “similar to (and coordinated with)” the foregoing marketing rules set forth in section 1851(h) with respect to Part D marketing. Specifically, organizations may not distribute marketing materials unless they have been submitted to CMS for review. Materials submitted for such review are deemed to be approved unless disapproved within 45 days, or 10 days when using model language specified by CMS. In reviewing marketing materials or election forms under § 422.2264 and § 423.2264, we ensure that marketing materials are provided in a format (with appropriate print size, as applicable) specified by CMS and will use standard terminology specified by CMS.

Our current marketing materials submission and review process encourages MAOs and PDP sponsors to use model materials to expedite the review and approval process. The model documents contain language provided by CMS, including language that is optional (or that can be modified), for plan use. Under this arrangement, MAOs and Part D sponsors may submit customized materials that reflect preferred word choices or phrasing tied to corporate messaging.

As marketing materials that describe plan benefits are critical to ensuring that beneficiaries make the best health care decisions for their particular needs, it is imperative that plan materials are accurate, free of errors, and comparable across MAOs and PDPs. Accordingly, in order to reduce variability of marketing

materials and to ensure documents are more accurate and understandable to beneficiaries, we propose to move toward greater standardization of the information provided in plan marketing materials. Specifically, we are proposing to revise § 422.2262 and § 423.2262 to require that MAOs and PDP sponsors use standardized marketing material language and format, without modification, in every instance in which we provide standardized language and formatting. We provide MAOs and PDP sponsors with standardized marketing materials through the annual Call Letter or Health Plan Management System (HPMS) memoranda. We believe this change would ensure beneficiaries receive more accurate and comparable information to make informed decisions about their health care options. This proposed change will also ensure increased efficiencies and greater consistency in our marketing material review protocols and processes.

4. Involuntary Disenrollment for Failure To Pay Plan Premiums Under Parts C and D (§ 422.74 and § 423.44)

Section 1851(g)(3)(B)(i) of the Act provides that MA organizations may terminate those MA plan enrollees who fail to pay basic and supplemental premiums within the grace period established by the MA organization. Section 1860D–1(b)(1)(B) of the Act generally directs us to use disenrollment rules for Part D sponsors that are similar to those established for MA organizations under section 1851 of the Act. Consistent with these sections of the Act, the Parts C and D regulations set forth our requirements with respect to involuntary disenrollment procedures under § 422.74 and § 423.44, respectively.

Currently, § 422.74(d)(1)(i)(B) specifies that an MA organization must provide, at minimum, a 1-month grace period before disenrolling individuals for failure to pay the premium. Similarly, under current regulations at § 423.44(b)(1)(i) and § 423.44(d)(1), Part D sponsors may disenroll an individual from a PDP for failing to pay PDP premiums on a timely basis, using the process set forth in the regulations. Unlike the statute, the Part D regulations do not specifically use the term “grace period,” but we have interpreted the regulations in the Medicare Managed Care Manual provisions (Section 40.3.1 of the Enrollment Chapter) to require that organizations provide beneficiaries a grace period of not less than 1 month, beginning on the first day of the month for which the premium is unpaid, before disenrollment for failure to pay premiums timely. For both Parts C and

D, these involuntary disenrollments are not mandatory; thus, organizations may choose to implement longer grace periods or forego involuntary disenrollments entirely.

However, MA organizations and Part D sponsors that choose to disenroll enrollees for failure to pay premiums must notify the enrollee of the delinquency and allow the enrollee an opportunity to resolve the delinquency within 30 days. Further, the organization or sponsor must also be able to demonstrate to us that it has made reasonable efforts to collect the unpaid premium amounts. Given the time required to notify the enrollee of the delinquency, for the enrollee to make payment, and for the payment to be received by the organization in cases where the organization has established the minimum grace period, the actual amount of time the enrollee has to resolve the delinquency may be less than one month.

A beneficiary who is disenrolled from his or her MA or Part D plan for failure to pay premiums is not eligible for a special enrollment period based on that disenrollment. This beneficiary may be unable to enroll in another plan until the next annual election period in the fall. This may leave a significant gap in coverage for MA–PD and PDP enrollees, since their disenrollment will likely leave them without prescription drug coverage for the remainder of the year, and in addition they potentially face a late enrollment penalty (LEP) should they subsequently choose to re-enroll in some type of Medicare prescription drug coverage. Given the possible risk to the health status of individuals that lose prescription drug coverage, as well as the LEP consequences, we propose to codify in regulations a stronger version of our existing policy.

Therefore, we are proposing to amend the regulations at § 422.74(d)(1) and § 423.44(d)(1) regarding disenrollment for nonpayment of premium to require a minimum grace period of 2 months before any involuntary disenrollment associated with failure to pay a premium. We further propose to codify the aforementioned manual provision regarding the beginning of the grace period for Part D. We believe that a 2-month period will provide adequate time for organizations to respond to instances in which individuals fail to pay their premiums, and for affected enrollees to take steps to remedy the situation and avoid disenrollment. We note that organizations would still be able to offer a more generous grace period than provided in the regulation, if they so choose.

5. Maximum Allowable Out-of-Pocket Cost Amount for Medicare Parts A and B Services (§ 422.100)

Under section 1852(b)(1) of the Act, we may not approve MA plans if we determine that the design of the plan and its benefits would substantially discourage enrollment by certain MA eligible individuals. Based on program experience and efforts to curb discriminatory benefit packages, we are proposing that all local MA plans include an annual out-of-pocket cap on members' total cost-sharing liability for Part A and Part B services, the amount of which will be set annually by CMS. Given that regional PPO plans already are required to have an annual cap on member out-of-pocket costs and that many local MA plans already have such limits, we believe that requiring the inclusion of such a limit in plan design is necessary in order to avoid discouraging enrollment by individuals who utilize higher than average levels of health care services (that is, in order for a plan not do be discriminatory in violation of section 1852(b)(1) of the Act).

While our concern about discriminatory or confusing benefit packages is longstanding, it has been particularly acute since the implementation of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) (Pub. L. 108–173). Since that time, plan offerings have become increasingly complex in terms both of cost sharing design and rules governing the application of cost sharing. For example, Health Maintenance Organization (HMO) plans may have a point of service benefit that allows the enrollee to obtain services out of network, but for higher cost-sharing levels. Preferred provider organization (PPO) plans are required to cover all plan services both in and out of network with typically higher out-of-network cost sharing. Members in private fee-for-service (PFFS) plans with a network may have differential cost sharing depending on whether they obtain services from a contracting or a deemed provider. Also, some coordinated care plans have introduced cost sharing “tiers” by which enrollees may be assessed different cost-sharing amounts depending on, for example, the plan contracted hospital from which they seek care. Because MA plans can vary in numerous ways, we are increasingly concerned that, faced with too many complex choices, beneficiaries are unable to confidently compare health plans and make meaningful choices. Because of these concerns, in the last

few years, we have used our authority under section 1852(b)(1) of the Act to scrutinize cost sharing and benefit designs offered by MA plans, and to require changes on a case by case basis where we found discriminatory cost-sharing. We also established out-of-pocket limits that, if adopted under an MA plan, would exempt the plan cost sharing from the same level of scrutiny it would otherwise receive.

For example, during the period since 2003, we have issued guidance: (1) Establishing an optional out-of-pocket maximum that plans could adopt which would result in less scrutiny of cost-sharing amounts for individual benefits under the plan; and (2) identifying certain health care services for special review that beneficiaries with higher than average health care needs are likely to need (for example, in-patient hospital, dialysis, skilled nursing facility (SNF), mental health services, Part B drugs and home health care).

To implement this guidance, we established a comprehensive process to review the proposed cost sharing of each plan benefit package and determine if the cost sharing design discriminates against those beneficiaries with higher than average health care needs. Specifically, we have conducted outlier analyses for the purpose of reviewing whether cost sharing levels on submitted benefit designs are discriminatory. We review, for example, the distribution of cost sharing levels submitted by MA organizations to identify the levels in the upper tail end of the range. This analysis assists us in determining the cost sharing threshold above which we consider the level to be discriminatory. We believe these efforts have resulted in some improvements in reducing discriminatory cost sharing and transparency of plan design. For example, including regional PPO plans, nearly 60 percent of all current MA plans have an out-of-pocket cap on beneficiary cost sharing with some local plans excluding certain services. Based on this experience, we believe that both a standard and mandatory cap on member cost sharing for all local MA plan types is an important and necessary step to ensure that plans are not discriminatory and beneficiaries are protected from unreasonable financial costs regardless of which MA plan they enroll.

Under our authority in section 1852(b)(1)(A) of the Act to ensure against MA plans that discriminate, our authority under section 1856(b)(1) of the Act to establish MA standards by regulation, and our authority under section 1857(e)(1) of the Act to add necessary and appropriate contract

terms, we propose to amend § 422.100(f)(3) by adding a new paragraph (f)(4) to specify that all local MA plans must establish an out-of-pocket maximum inclusive of all Medicare Parts A and B services that is no greater than the annual limit set by CMS. The cap for local PPO plans will be inclusive of all in-network and out-of-network beneficiary cost sharing. The methodology for determining the out-of-pocket maximum for local MA plans will be similar to the methodology we used to establish the voluntary out-of-pocket maximum amount for MA plans for contract year 2010. The out-of-pocket maximum will be set at a certain percentile of expected FFS spending, and this amount will be estimated by the Office of the Actuary (OACT). We summarized the methodology used to determine the voluntary out-of-pocket maximum for MA plans for contract year 2010 on page 13 of the 2010 Call Letter. As summarized in the 2010 Call Letter, MA out-of-pocket threshold is based on a beneficiary-level distribution of Parts A and B cost sharing for individuals enrolled in Original Medicare. The CY 2010 out-of-pocket threshold of \$3,400 represents the 85th percentile of projected beneficiary spending in 2010. We do not expect an impact on cost-sharing and premiums, all other things being equal, for plans that already provide for an out-of-pocket maximum. However, requiring all plans to have an out-of-pocket maximum will likely result in increases to premiums and/or cost-sharing, although we are not able to quantify the extent of this increase. We propose to continue to furnish information to MA organizations on our methodology and the amounts for acceptable out-of-pocket caps on a timely basis through the annual Call Letter or Health Plan Management System (HPMS) memoranda. We solicit comments on this approach.

6. Maximum Allowable Cost Sharing Amount for Medicare Parts A and B Services and Prescription Drugs (§ 422.100, § 423.104)

We have always reviewed cost sharing levels for individual services for the purpose of determining whether or not such levels are discriminatory. Based on our experience, in which we annually review the levels of cost sharing across all bids, we propose to amend our regulations on the general requirements related to MA benefits and qualified prescription drug coverage to expressly authorize us to establish cost sharing thresholds for individual services below which cost sharing will be considered non-discriminatory. We believe that requiring the inclusion of such cost

sharing thresholds in plans' benefit designs affords greater predictability and protection against high out-of-pocket costs for beneficiaries with medical conditions that could result in exceptionally high out-of-pocket costs obligations, and further ensures that those beneficiaries are not discouraged from enrolling in an MA plan.

Under Part C, we propose annually to review bid data to determine specific cost sharing levels for Medicare A and B services below which would not have a discriminatory effect, and therefore may be approved in an MA benefit package. Similarly, under Part D, we would annually review bid data to determine acceptable cost sharing tiers for non-defined standard benefit designs. We will furnish information to MA organizations and Part D sponsors on its methodology and the acceptable cost sharing amounts based on the prior year's bids on a timely basis either through the annual Call Letter or Health Plan Management System (HPMS) memoranda. The methodology for determining the cost-sharing thresholds for Part A and B services will involve reviewing the prior year's bid data, as well as actuarial equivalencies from original Medicare, to determine outliers. These amounts could be adjusted based on new bid submissions for the current year.

We propose to determine these acceptable cost sharing levels based on factors such as distribution of cost sharing among submitted bids, comparison to Original Medicare cost sharing (in the case of Part C), and other factors that we find to assist in identifying discriminatory levels of cost sharing (for example, the number of tiers in the case of a Part D plan). A sponsoring organization's cost sharing will be considered discriminatory if it is higher than the maximum level that we determine to be non-discriminatory for a particular service in the case of an MA plan or a drug cost tier in the case of a Part D plan. We will communicate expected discriminatory cost sharing thresholds to sponsoring organizations through the annual Call Letter or HPMS memoranda during the annual bid and benefit package review process. These thresholds will be based on the prior year's experience and may be adjusted based on bid submissions for the current year. We solicit comment on this approach, including the extent to which we have provided sufficient clarity on how we determine whether cost-sharing levels are discriminatory.

Organizations submitting MA plan or prescription drug plan bids found to have discriminatory cost sharing will have an opportunity to resubmit their

bid and benefit package to comply with our non-discrimination requirements. We will annually evaluate our review process and the criteria we use to determine cost sharing discrimination and may make changes to ensure that beneficiaries are protected from discriminatory cost sharing.

We propose to amend § 422.100 by adding a new paragraph (f)(5) to specify that cost sharing for Medicare A and B services may not exceed levels annually determined by CMS to be discriminatory. Additionally, we propose to revise § 423.104(d)(2) by adding a new paragraph (iii) to specify that tiered cost sharing for non-defined standard benefit designs may not exceed levels annually determined by CMS to be discriminatory.

7. Prohibition on Prior Notification by PPO, PFFS and MSA Plans Under Part C (§ 422.2, § 422.4, and § 422.105(b))

In the preamble of the Medicare Program; Establishment of the Medicare Advantage Program final rule published in the January 28, 2005 **Federal Register** (70 FR 4598 through 4599), as well as in the 2009 and 2010 Call Letter, <http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/CallLetter.pdf> and <http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/2010CallLetter.pdf>, respectively, we provided guidance permitting local and regional PPO plans (for out-of-network services) and PFFS plans to provide for lower cost sharing amounts in cases in which an enrollee or provider voluntarily gives the MA organization with prior notification that the service will be received. We also made clear that PPO plans (for out-of-network services) and PFFS plans may not require such notice, or prior authorization or referrals from gatekeepers, as a condition of coverage in order to restrict an enrollee's access to services. As stated below, Medical Savings Account (MSA) plans similarly may not impose prior authorization requirements as a condition of coverage. Under prior authorization, a plan requires an enrollee to seek its approval before obtaining services from a provider; if the enrollee does not obtain prior approval, then the plan can deny coverage for the service. We provided additional guidance to PPO and PFFS plans on how they must explain to current and prospective enrollees the plan's standard cost sharing and the reduced cost sharing related to prior notification.

However, since that time, we have become increasingly concerned about the use of prior notification by PPO and

PFFS plans. Program experience has demonstrated that prior notification is confusing to beneficiaries, misleading in terms of disclosure of cost-sharing, and, in some instances, used inappropriately as a form of prior authorization. In the GAO report titled "Medicare Advantage: Characteristics, Financial Risks, and Disenrollment Rates of Beneficiaries in Private Fee-for-Service Plans (GAO-09-25)," the GAO noted that some PFFS plans it reviewed "inappropriately used the term prior authorization rather than pre-notification in the informational materials they distributed to beneficiaries, which may have caused confusion about beneficiaries' financial risks." We have concluded that the complexity of cost sharing designs using prior notification has made it more difficult for both enrollees and providers to understand the enrollee's cost sharing obligation in advance of receiving services. Therefore, in order to reduce the complexity of MA plans' cost sharing designs and improve transparency for both enrollees and providers, we are proposing to prohibit PPO plans (for out-of-network services) and PFFS plans from providing for lower cost-sharing where prior notification rules have been satisfied. We propose to revise § 422.4(a)(1)(v) and (a)(3) to provide that PPO and PFFS plans will be prohibited from establishing prior notification rules under which an enrollee is charged lower cost sharing when either the enrollee or the provider notifies the plan before a service is furnished.

We also propose to prohibit MSA plans from establishing prior notification rules. The definition of a MSA plan in section 1859(b)(3)(A)(iii) of the Act ensures open access to services for MSA enrollees without restriction to a provider network and without prior authorization reviews for health care services. MSA plans may have networks of providers, but may not restrict an enrollee's access to those network providers. We believe that prior notification rules established by MSA plans would also be confusing to enrollees of those plans and have similar negative effects as those described above for PPO and PFFS plans. We propose to modify § 422.4(a)(2) such that MSA plans will also be prohibited from establishing prior notification rules under which an enrollee is charged lower cost sharing when either the enrollee or the provider notifies the plan before a service is furnished.

In the preamble of the Medicare Program; Establishment of the Medicare Advantage Program final rule published in the January 28, 2005 **Federal Register**

(70 FR 4617 through 4619), we discussed rules related to point of service (POS) options that are offered by some MA organizations. We stated that PPOs may offer a POS-like benefit under which beneficiary cost sharing would be less than it would otherwise be for non-network provider services, but still might be greater than it would be for in-network provider services, provided an enrollee follows preauthorization, pre-certification, or prenotification rules before receiving out-of-network services. We also noted that such preauthorization, pre-certification, or prenotification cannot be a necessary condition for receipt of, or required MA plan reimbursement for, out-of-network covered services by a PPO enrollee, but that it could act as a financial incentive (by lowering the normal out-of-network cost sharing that would otherwise apply) to an enrollee to voluntarily participate. Similar to our concerns about the use of prior notification rules by PPO and PFFS plans, as discussed above, we believe that the complexity of cost sharing designs for PPO plans with a POS-like benefit make it more difficult for both enrollees and providers to understand the enrollee's cost sharing obligation in advance of receiving services. In order to reduce the complexity of PPO plans' cost sharing designs and improve transparency for both enrollees and providers, we are proposing to prohibit PPO plans from offering a POS-like benefit. We propose to revise the definition of POS in § 422.2 and § 422.105(b) to indicate the only HMOs may offer a POS benefit. The proposed change is consistent with section 1851(a)(2)(A)(i) of the Act, which states that an HMO may include a POS option.

Although PPO (for out-of-network services), PFFS, and MSA plans may not impose prior authorization and referral requirements as conditions for covering services, enrollees and providers have the right to request a written advance coverage determination from the plan, in accordance with Subpart M of Part 422, before an enrollee receives a service in order to confirm that the service is medically necessary and will be covered by the plan.

8. Requirements for LIS Eligibility Under Part D (§ 423.773)

Section 423.773(c) specifies that the individuals treated as full subsidy eligible individuals include the following:

- Full-benefit dual eligible individuals;
- Supplemental Security Income (SSI) recipients under Title XVI of the Act; and

- Individuals eligible for Medicaid as a Qualified Medicare Beneficiary, Specified Low-Income Medicare Beneficiary, or a Qualifying Individual under a State's Medicaid plan.

In § 423.773(c)(2), we are proposing to amend the length of the period for which individuals are re-deemed eligible for the full low income subsidy to conform with guidance we issued in section 40.2.2 of Chapter 13 of the Medicare Prescription Drug Benefit Manual. Section 423.773(c)(2) currently specifies that a full subsidy eligible individual is deemed eligible for the full subsidy for a period up to 1 year. However, in practice, the period of deemed eligibility varies from as little as 7 months to as long as eighteen months, depending on when the individual attained deemed status (that is, became eligible for Medicaid, a Medicare Savings Program, or for SSI).

Every year, we review data from State Medicaid Agencies and the Social Security Administration (SSA) sent to us in July and August, respectively, to determine whether individuals currently deemed eligible for the subsidy should continue to be deemed (that is, "re-deemed") eligible for the subsidy. This allows us sufficient time to update individuals' records in our systems, if necessary, and to notify them if they are losing deemed status, so that they can take the appropriate steps to apply for the subsidy, in time for coverage to be effective at the start of the new calendar year.

When we are reviewing data in July and August, we also identify individuals who are newly eligible for Medicaid, a Medicare Savings Program, or SSI, and deem these individuals eligible for the subsidy for the remainder of the current calendar year. We also redeem these individuals for the subsidy for the next calendar year, because we do not have sufficient time in the final months of the year to conduct a separate redeeming process for these individuals. If we waited to redeem these beneficiaries after the start of the calendar year, they could incur greatly increased premium liability and cost sharing amounts at the start of the new calendar year than they would have otherwise.

For example, if a State Medicaid Agency submits data to CMS indicating an individual is eligible for Medicaid in March of a given year, and that individual is Part D eligible, we deem that individual eligible for the Part D low income subsidy from March 1st through December 31st of that year. We redeem that individual for the following calendar year only if we receive subsequent information from the State

or SSA indicating that the individual remains eligible for Medicaid, a Medicare Savings Program, or SSI.

On the other hand, if a State submits data to CMS indicating that an individual is eligible for Medicaid in July or a later month of a given year, and the individual is Part D eligible, we deem the individual eligible for the Part D subsidy for the remainder of that calendar year and all of the following calendar year. (See section 40.2.2 of Chapter 13 of the Medicare Prescription Drug Benefit Manual.) Therefore, we propose to amend § 423.773(c)(2) to indicate that the deeming will be, at a minimum, for the following periods: If deemed status is determined between January 1st and June 30th of a calendar year, the individual is deemed subsidy eligible for the remainder of the calendar year. If deemed status is determined between July 1st and December 31st of a calendar year, the individual is deemed subsidy eligible for the remainder of the calendar year and the next calendar year. We believe this change will streamline the deeming/redeeming process and decrease the administrative burden on agencies and subsidy eligible individuals.

9. Enrollment of Full Subsidy Eligible Individuals and Other Subsidy Eligible Individuals Under Part D (§ 423.34)

In the January 28, 2005 **Federal Register**, when we issued the Medicare Prescription Drug Benefit final rule (70 FR 4193), we added § 423.34 to describe our procedures for enrollment of full-benefit dual eligible individuals. We discussed how full-benefit dual eligible individuals are enrolled, which PDPs they are assigned to, and the effective date of their enrollment. As noted in the preamble to the final regulation, enrollment of other low-income subsidy (LIS) eligible individuals would also be conducted, and details would be issued in operational guidance. However, we did not incorporate into the initial Part D regulations further detail about the enrollment procedures that would apply to this remaining population of LIS-eligible individuals.

Section 1860D-1(b)(1)(A) of the Act directs the Secretary to establish a process for the enrollment of Part D eligible individuals. As we indicated in the preamble to the January 28, 2005 final rule (70 FR 4209), while the statute does not explicitly provide for the auto-enrollment of other LIS-eligible individuals into the Medicare Part D program, we believe that enrolling these individuals clearly is consistent not only with statutory intent but also with the intent of the individuals themselves.

The express purpose of applying for the Part D low-income subsidy is to obtain prescription drugs on a subsidized basis, which can only be accomplished through enrollment in a Part D plan. Therefore, we established a separate enrollment process for these individuals known as “facilitated enrollment.” We randomly assign these individuals to a PDP in their area with a premium below the low-income benchmark and notify these individuals that they may choose a Part D plan on their own and that if they do not choose a plan, we will enroll them in a plan in their area. We have been carrying out the “facilitated” enrollment process for more than 3 years without objections from beneficiaries or from the advocacy community; in fact, we believe that many individuals are under the mistaken impression that being approved for the subsidy actually equates with enrolling in a plan, so we believe our proposal will help rectify that problem. (See section 30.1.4 of Chapter 3 of the Medicare Prescription Drug Benefit Manual for more information about facilitated enrollment).

Based on this experience, we believe it would be appropriate to codify in regulation the enrollment procedures that we use for these individuals, which are similar to those specified in the regulation for the dual eligible population. We believe that our regulations would be more accurate and complete if they specifically addressed this population. Thus, we are proposing to amend § 423.34 to reflect the guidance we have issued in Chapter 3 of the Prescription Drug Program Manual. Specifically, we are proposing to include information on how we enroll all LIS-eligible individuals, including full-benefit dual eligible individuals.

We are proposing the following revisions to § 423.34:

- In § 423.34(a), we propose to expand the general rule to refer to all LIS-eligible individuals, so that the rest of that section applies not only to full-benefit dual eligible individuals, but also to all LIS-eligible individuals.

- In § 423.34(b), we would retain the definition of full-benefit dual eligible individual, and add a definition for “low-income subsidy eligible individual.”

- We propose to amend the paragraph heading of § 423.34(c) to indicate that this paragraph describes the process we use to reassign LIS individuals during the annual coordinated election period. We would indicate that the reassignment process applies to certain low-income subsidy eligible individuals

(that is, not just full benefit dual eligible individuals).

- We are proposing to revise the paragraph heading of § 423.34(d) from “Automatic Enrollment Rules” to “Enrollment Rules.” We are proposing this change to reflect the inclusion of full subsidy and other subsidy eligible groups in this enrollment process, in addition to full-benefit dual eligible individuals. In our guidance, we refer to the process of enrolling full-benefit dual eligible individuals as “automatic enrollment,” and the process for other LIS eligibles as “facilitated enrollment.” (See section 30.1.4 of Chapter 3 of the Medicare Prescription Drug Benefit Manual.)

- We propose to amend § 423.34(e) to indicate that the rules regarding declining enrollment and disenrollment also apply to all LIS-eligible individuals.

- In § 423.34(f), we would clarify that the paragraph heading and contents of this paragraph are limited to the effective date of enrollment for full-benefit eligible individuals. We propose to amend § 423.34(f)(3) to specify that, for individuals who are eligible for Part D and subsequently become eligible for Medicaid on or after January 1, 2006, the effective date of enrollment would be the first day of the month the individual becomes eligible for both Medicaid and Medicare Part D.

- In § 423.34(g), we propose adding a new paragraph to specify that the effective date for low income subsidy eligibles who are not full benefit dual eligibles would be no later than the first day of the second month after we determine that the individual meets the criteria for enrollment into a PDP under this section. This change conforms to section 30.1.4 of Chapter 3 of the Medicare Prescription Drug Benefit Manual. Unlike full benefit dual eligible individuals who may have retroactive Part D coverage, these individuals have only prospective Part D coverage.

Although we believe that all these provisions will benefit the LIS-eligible population, we recognize that concerns have been raised about the impact of the current random auto-enrollment process on affected beneficiaries. For example, focus groups of seniors suggest the possibility that some auto-enrolled beneficiaries may not realize they have been enrolled in a drug plan or that they have been reassigned to a different drug plan. We are committed to taking appropriate steps to improve this process. Thus, we welcome comments related to all aspects of these procedures, including comments on issues such as the following:

- The efficacy of the existing auto-enrollment and facilitated enrollment procedures, and suggestion for improving these procedures;
- Ways to assess the impact of these procedures on the dual eligible and LIS population, including the costs, benefits, and potential unintended consequences. For example, is it possible that seniors who are LIS-eligible but not eligible for Medicaid will not realize that they have been auto-enrolled into a drug plan? Is there any possibility that auto-enrolling these individuals could ever lead to delinquencies in payments? Given that LIS-eligible individuals are auto-enrolled into plans with premiums below the benchmark, we do not believe these individuals would ever become subject to premium issues or liable for other such costs that they are not aware of in advance. However, we welcome comment on whether the possibility exists and, if so, how payment delinquencies should be handled in this vulnerable population.

- How we can better assist beneficiaries in identifying plan choices that best suit their individual drug needs, and encourage them to make an active election.

10. Special Enrollment Periods Under Part D (§ 423.380)

Consistent with the changes in § 423.34, we are proposing to expand the special enrollment period described in § 423.38(c)(4), which currently applies to full-benefit dual eligible individuals, to all LIS-eligible individuals. This change is consistent with our authority in section 1860D–1(b)(3)(C) of the Act and would conform our regulations to current practice as reflected in CMS guidance in section 20.3.8, item 7, of chapter 3 of the Medicare Prescription Drug Benefit Manual.

11. Transition Process Under Part D (§ 423.120(b)(3))

Section 1860D–11(d)(2)(B) of the Act gives the Secretary authority similar to that of the Director of the Office of Personnel Management with respect to health benefits plans under chapter 89 of title 5, United States Code. This includes the authority to “prescribe reasonable minimum standards for health benefits plans.” In addition, section 1860D–11(e)(2)(D) of the Act prohibits us from approving a plan if “the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain part D eligible individuals.”

Under the authority of section 1860D-11 of the Act, we established a requirement in the January 28, 2005 final rule implementing the Part D program that requires sponsors of Part D plans to provide for an appropriate transition process for new enrollees prescribed Part D drugs that are not on its plan's formulary (70 FR 4264). We further specified in regulation that the transition policy must be consistent with written policy guidelines and other CMS instructions. The transition requirement is codified in at § 423.120(b)(3).

Following publication of the regulation, we issued guidance in 2005 on what constituted an appropriate transition process for new Part D enrollees. We noted in our guidance that an appropriate transition process was one that balances the protection of certain vulnerable populations with the flexibility necessary for Part D plans to develop a benefit design that promotes beneficiary choice and affordable access to medically necessary drugs. We updated the transition guidance for contract year 2007 as part of the 2007 Call letter, noting that the transition guidance represented a minimum set of standards for a Part D sponsor transition process. This guidance was incorporated into Chapter 6 of the Medicare Prescription Drug Benefit Manual located at <http://www.cms.hhs.gov/PrescriptionDrugCovContra/downloads/R2PDBv2.pdf>.

Our experience has shown that transition processes represent an important enrollee protection to ensure access to needed Part D drugs. Given the movement from year to year of some dual eligible beneficiaries due to reassignment, and the annual bidding cycle related to Part D plan offerings in which benefits and formularies may be modified, we believe that some protections are necessary for plan enrollees with immediate prescription needs who experience a change in enrollment or who experience formulary changes under their existing plan at the beginning of a contract year. These protections are particularly important when an individual first presents at a participating pharmacy with a prescription for a drug that is not on the formulary, unaware of what is covered by the plan or of the sponsor's exceptions process for providing access to Part D drugs that are not on the plan's formulary. For example, a full-benefit dual eligible enrollee who is auto-enrolled into a plan may not make an affirmative choice based on review of a plan's benefit relative to his existing medications needs. For these types of

situations, we directed Part D sponsors to have systems capabilities to allow them to provide a one time, temporary supply of non-formulary Part D drugs (including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a sponsor's utilization management rules) in order to accommodate the immediate needs of an enrollee, as well as to allow the sponsor and/or the enrollee sufficient time to work out with the prescriber an appropriate switch to a therapeutically equivalent medication or the completion of an exception request to maintain coverage of an existing drug based on medical necessity reasons. Our guidance has developed over time in response to these concerns, and we believe it strikes the right balance between enrollee protection and plan flexibility.

Given the importance of our transition policy as an enrollee protection—particularly for auto-assigned and reassigned beneficiaries who did not affirmatively choose a Part D plan—we propose to codify in regulation certain policies from our guidance on the necessary elements of a plan transition process. We also believe that any plan that fails to meet its transition policy requirements discourages enrollment (or re-enrollment) by Part D eligible individuals that may currently be taking prescription drugs that are not on the plan's formulary. Accordingly, we propose that a Part D sponsor must provide for a transition for the following:

- New enrollees into PDPs following the annual coordinated election period;
- Newly eligible Medicare enrollees from other coverage;
- Individuals who switch from one plan to another after the start of the contract year; and
- Current enrollees remaining in the plan who are affected by formulary changes from one contract year to the next.

Our experience thus far has shown that these groups represent the minimum target populations that are most likely to require protections to ensure immediate access to their prescription drug benefit.

We also propose, consistent with our current guidance, that a Part D sponsor's transition process requirements be applicable to non-formulary drugs, meaning both: (1) Part D drugs that are not on a sponsor's formulary; and (2) Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a plan's utilization management rules. The latter is included because a formulary drug to which access is

restricted via utilization management requirements is essentially equivalent to a non-formulary Part D drug to the extent that the relevant utilization management requirements are not met for a particular enrollee.

Additionally, we propose, consistent with our current guidance, to codify the timeframes for the transition process and the days' supply limit for a transition fill of an enrollee's medication. Our guidance was premised on the position that it made sense to limit the amount of time during which a transition process is applicable to new enrollees to the first 3 months under the plan as we believed an enrollee unfamiliar with his or her plan's formulary requirements would likely to present with a prescription during the first few months enrolled. We also propose to codify the transition process timeframe to apply during the first 90 days of coverage under a new plan. This 90-day timeframe would apply to retail, home infusion, long-term care, and mail-order pharmacies.

We also propose to require plans to provide a temporary supply of drugs under their transition process. As we noted in our original transition guidance to Part D plan sponsors in Chapter 6 of the Medicare Prescription Drug Benefit Manual, providing a temporary supply represented the most efficient method of triaging requests for filling initial prescriptions of non-formulary drugs for large numbers of new enrollees who, despite education efforts to make them aware of the plan's benefit, may not be aware of which drugs are listed on the plan's formulary. Consistent with Chapter 6, we propose that Part D plan sponsors must ensure that the one-time, temporary supply of non-formulary Part D drugs requested during the first 90 days of coverage in an outpatient setting must be for at least 30 days of medication, unless the prescription is written by a prescriber for less than 30 days, in which case the Part D sponsor must allow multiple fills to provide up to a total of 30 days of medication. For a new enrollee in a Long term Care (LTC) facility, the temporary supply may be for up to 31 days (unless the prescription is written for less than 31 days), consistent with the dispensing practices in the LTC industry. In addition, due to the often complex needs of LTC residents that often involve multiple drugs and necessitate longer periods in order to successfully transition to new drug regimens, sponsors must honor multiple fills of non-formulary Part D drugs, as necessary during the entire length of the 90-day transition period. This is particularly important if transitions to

formulary drugs have not been effectuated prior to the refills. We propose to require up to a 31-day transition supply for enrollees in an LTC facility given that many LTC pharmacies and facilities dispense medication in 31-day increments. Thus, a Part D sponsor would be required to provide a LTC resident enrolled in its Part D plan at least a 31 day supply of a prescription when presenting in the first 90 days of enrollment (unless the prescription is written for less) with refills provided, if needed, up to a 93 day supply.

In addition to codifying the preceding requirements, we also propose to take the opportunity in this rulemaking to clarify our expectations of sponsors with respect to providing transition notices. Based on our experience overseeing the Part D program, we have learned that a successful transition process is contingent upon informing enrollees and their caretakers about their options for ensuring that enrollees' medical needs are safely accommodated within a Part D sponsor's formulary. An enrollee who receives a temporary supply of a non-formulary Part D drug at a network pharmacy might simply assume that, by virtue of filling his or her prescription, the plan will cover that drug for the remainder of the contract year. For this reason, we are proposing to require sponsors to provide enrollees with appropriate notice regarding their transition process within a reasonable amount of time after providing a temporary supply of non-formulary Part D drugs (including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a sponsor's utilization management rules).

Our guidance specifies that Part D sponsors send a written notice, via U.S. First Class mail, to each enrollee who receives a transition fill. This standard is consistent with our requirement that other enrollee communications, including formulary change notices and explanations of benefits, be sent via U.S. First Class mail. In addition, our guidance directs sponsors to send this notice to each affected enrollee within 3 business days of the temporary fill. Our rationale for this turnaround time is that it is necessary in order to provide an affected enrollee with sufficient time—especially in light of our 30-day transition fill policy in the outpatient setting to work with his or her prescriber to switch to a therapeutically equivalent drug that is on the plan's formulary or to process an exceptions request.

Given the importance of enrollee access to medications, especially during

a transition in coverage, or a transition in a level of care, we propose to codify this portion of our guidance and require provision of transition notices.

However, in addition to this codification, we also propose to require plan sponsors to make reasonable efforts to notify prescribers, via mail, electronic or verbal communication, that the affected enrollees' prescription cannot be refilled, either because of utilization management requirements such as prior authorization or step therapy, or because the prescribed medication is not on the plan sponsor's formulary. We believe that this communication is necessary in order to expedite the prescriber's plan to seek therapeutic alternatives for the enrollee or to fill out the requisite paper work to submit to the Part D sponsor to initiate the exceptions process. We invite comments on this proposal.

Accordingly, we propose the following revisions to § 423.120(b)(3):

- Add paragraph (3)(i) to clarify which enrollees the transition process should apply;
- Add paragraph (3)(ii) to ensure access to a temporary supply of drugs within the first 90 days of coverage under a new plan;
- Add paragraph (3)(iii) to provide a temporary fill when an enrollee requests a fill of a non-formulary drug during the time period specified in paragraph (ii) (including Part D drugs that are on a plan's formulary but require prior authorization or step therapy under a plan's utilization management rules) and the days supply in the outpatient setting must be for at least 30 days of medication. In the long-term care setting, the temporary supply must be for up to 90 days in 31 day supply increments;
- Add paragraph (3)(iv) to ensure written notice is provided to each affected enrollee within 3 business days of the temporary fill;
- Add paragraph (3)(v) to ensure that reasonable efforts are made to notify prescribers of affected enrollees who receive a transition notice under paragraph (iv).

12. Part D Sponsor Responsibility for Retroactive Claims Adjustment Reimbursements and Recoveries Under Part D (§ 423.464)

Sections 1860D–23 and 1860D–24 of the Act require PDP sponsors to coordinate with state pharmaceutical assistance programs (SPAPs) as well as other drug plans, including Medicaid programs, group health plans, Federal Employee Health Benefit Plans (FEHBP), military coverage and other plans or programs providing

prescription drug coverage. These requirements are codified at § 423.464 and set forth in the Medicare Prescription Drug Benefit Manual. As we have gained more experience with the prescription drug program, we have found that some beneficiary changes (for example, those resulting from retroactive low income subsidy LIS eligibility determinations, LIS status changes, or midyear Part D enrollment changes) that necessitate retroactive claims adjustments are a significant issue under Part D. These changes, as well as long-term care pharmacy billing practices for dual-eligible beneficiaries and the presence of secondary, tertiary and even quaternary payers have all contributed to a higher than expected volume of retroactive claims adjustments requiring Part D sponsor reimbursements and recoveries, as well as a greater than anticipated complexity of calculating these amounts. While we previously anticipated that beneficiaries would be owed reimbursements due to changes in LIS status, and required plan sponsors to make such reimbursements in § 423.800(c), we have since learned that our current regulations do not reflect the other entities that may sometimes need to be taken into account in reimbursement or recovery transactions. Moreover, we have also learned that no industry standard electronic process exists to explicitly handle underpayment recoveries or overpayment reimbursements created by these adjustments, and that the current Health Insurance Portability and Accountability Act (HIPAA) standard for coordination of benefits for pharmacy claims only partly supports these activities when the pharmacy initiates “reverse and rebill” transactions. As a result, we are aware that Part D sponsors are sometimes struggling with how to manage these retroactive adjustments and that those sponsors that are refunding overpayments or seeking underpayment recovery are each doing it differently.

Since current regulations do not address retroactive adjustments and the complexities associated with coordination of benefit activities that cannot be accomplished between the Part D sponsor and the pharmacy through reversal and re-billing, we have issued general guidance to direct sponsor coordination of benefit activities. Sections of the COB and LIS chapters of the Medicare Prescription Drug Benefit Manual specify standards for a PDP sponsor to: work with other providers of prescription drug coverage to resolve payment issues; have a process in place to handle the payment

resolution that is not restricted by implementation of timely filing requirements; make retroactive adjustments and promptly refund monies owed to the correct party (including, but not limited to the beneficiary); and generally limit requests for pharmacy reprocessing to those situations involving a pricing error. Additionally, CMS guidance includes as part of the coordination of benefits the transfer of true out-of-pocket (TrOOP) costs and gross covered drug cost data to a new Part D plan when a beneficiary changes enrollment during the coverage year. In our October 20, 2008 Part D sponsor implementation guidance on the automated process for the transfer of these TrOOP-related data, we established a 45-day maximum time limit from receipt of a post-adjudicative change in the reported data for the sponsor to take adjustment action, make a refund, and/or initiate recovery. We established this time limit after an informal survey and discussions with Part D sponsors and their processors. While some entities indicated they were making adjustments more frequently, the industry generally supported a 90-day limit, which is consistent with the time limit on pharmacy claim reversals. However, we believe this longer timeframe is not in the best interests of the beneficiary because it would delay the payment of refunds and notification of the need for payment recovery. On the other hand, because many of the claims reversals occur early in the 90-day period, a very short adjustment timeframe could lead to a series of consecutive refunds and recoveries that would be confusing and, therefore, also not in the best interests of the beneficiary. Accordingly, we believe that a 45-day time limit represents a reasonable compromise.

Many of the post-adjudicative adjustments, such as those that are due to enrollment changes, are changes that affect beneficiary cost-sharing, premiums and/or plan benefit phase. Establishing a reasonable time limit for all Part D adjustment, refund, and recovery activity is in the beneficiaries' best interests because it ensures that required changes are effectuated on timely basis, thus correcting retroactive and prospective beneficiary premium and cost-sharing amounts. Moreover, it is in the best interest of others who have paid a claim, or are holding a balance due, on the beneficiary's behalf because it ensures that these amounts are resolved timely.

At § 423.464 and § 423.466, we are proposing to codify our previous policy guidance (for instance, our memorandum on plan LIS changes

dated October, 30, 2006) by proposing that sponsors must both make retroactive claim adjustments and take other payer contributions into account as part of the coordination of benefits. Further, we are also proposing to add a new timeliness standard at § 423.466 to require adjustment and issuance of refunds or recovery notices within 45 days of the sponsor's receipt of the information necessitating the adjustment. While claims adjustments must be made and notices issued within the established timeframes, we continue to recognize that calculating the precise amount of the adjustment and any resulting reimbursements or recoveries may not always be practicable due to limitations in the electronic transaction set and contractual terms and conditions for payment in use in the pharmacy industry. However, sponsors must exercise due diligence in fulfilling these requirements.

To date, most Part D coordination of benefits activity has been performed at point-of-sale or soon after, so pharmacy reversal and rebilling of claims can be accomplished within the payers' timely filing windows. For Part D, this window must be a minimum of 90 days, but for other (non-Part D) providers of prescription drug coverage the filing window could be as short as 30 days. With the instability of LIS data and Part D enrollments creating a significant volume of retroactive adjustments, it has become evident that sponsors are facing more claims adjustments than current pharmacy claim reversal and rebilling approaches can adequately address.

Online real-time coordination of benefits, in which the order of payment among multiple payers is established and programmed into payer systems, generally did not take place in pharmacy benefit management prior to Part D implementation. Therefore, following the issuance of the Medicare Prescription Drug Benefit final rule on January 28, 2005, CMS and the industry, in collaboration with the National Council for Prescription Drug Programs (NCPDP), collaborated to develop an electronic process consistent with HIPAA-authorized transaction standards to allow supplemental payer information to be available at point-of-sale and patient-pay amounts remaining after supplemental payer payments to be reported back to the primary Part D sponsor for purposes of tracking TrOOP. However, by design, all billing transactions still require the pharmacy to initiate the activity. What this means in the case of a claims adjustment is that if the beneficiary is no longer at the counter and a supplemental payer's claim filing window is closed, the

pharmacy can no longer effectively coordinate benefits between payers. And payers cannot effectively coordinate among themselves, both because of the absence of electronic standards for post-adjudication claim adjustments among payers (as opposed to between pharmacies and payers), and the presence of contractual prohibitions between payers and pharmacies on the disclosure of proprietary pricing information. Therefore, at the present time, CMS and the industry are struggling to determine how best to handle retroactive claims adjustments whenever the adjustment cannot be resolved simply between the sponsor and the pharmacy.

Pharmacies regard their pricing information as proprietary and are concerned about the potential chilling effect any disclosure of this information might have on their ability to negotiate with payers. Therefore, to ensure the confidentiality of pricing information, coordination of benefits on the initial claim is accomplished without reporting complete information on negotiated pricing. The amount reported in the transaction to the Part D plan is the amount of the beneficiary payment after the supplemental payment. As a result, a Part D sponsor attempting to determine refund or recovery amounts without having the pharmacy reverse and rebill the original claim can generally only impute the amount of any supplemental payment made by another payer by determining the difference between the Part D cost-sharing and the beneficiary amount paid after the supplemental payment. The only alternative is to ask the pharmacy to reverse and rebill the claim to all payers. However, this procedure is generally unreasonable after the industry standard 30-day window because many supplemental payers will not accept the late claim and, as a consequence, the pharmacy would be left short the supplemental payer payment amount, as well as any difference in beneficiary cost sharing that might be due.

In the absence of legal authority to compel supplemental payer cooperation and to avoid pharmacy underpayment, imposing a requirement on sponsors to nonetheless calculate a precise reimbursement or recovery liability would require the creation of a new payer-to-payer transaction that both enables reprocessing and addresses pharmacies' concerns about revealing their proprietary pricing. It is not clear that both goals can be achieved. Nor is it clear that even if this conflict could be resolved, that the cost of doing so would be justified by the benefits. That

is, it is not clear to us that the benefits of more precisely calculating the differential amounts owed or due (the incremental amounts more or less that supplemental payers and beneficiaries would have paid if the correct LIS subsidy had been applied to the original claim) outweigh the costs of developing customized electronic transactions for such calculations. This is because while some adjustments are from non-subsidized to subsidized cost sharing, many others only change patient pay amounts after the Part D plan payment by a dollar or two, and many would not change the beneficiary cost sharing at all because the difference would be picked up by or owed to a supplemental payer. Thus, despite the importance of accurate reimbursement to all parties, the cost of developing specialized transactions may outweigh the benefits that would accrue.

Some supplemental payers are cooperating in the exploration of a solution through NCPDP, for example, certain SPAPs, but others continue to close their claims filing window at 30 days and permit no further coordination. Part D sponsors and/or their claim processors are likewise currently engaged with CMS through NCPDP in examining the scope of the problem and exploring alternative approaches to retroactively and electronically adjust claims. However, at this time, while simple adjustments involving just the Part D sponsor and the pharmacy are relatively straightforward (and can and should be promptly transacted), those involving other payers are not. Thus, we continue to hold the plans accountable for making best efforts to coordinate benefits occasioned by claim adjustments, but we acknowledge that electronic transaction standards have not yet been developed to support timely, reliable, and precise coordination on adjusted claims when multiple payers are involved. Therefore, we will continue to work with the industry on methods to make best efforts in this area, including limiting other payer recoveries and reimbursements to imputed amounts due to and from supplemental payers that choose to fully cooperate with industry consensus-driven processes developed through NCPDP. We note that amounts due to or from beneficiaries must also be imputed in some of these situations. We are soliciting comments on alternative approaches to improving post-adjudication coordination of benefits necessitated by retroactive Medicare enrollment and low-income subsidy

changes when multiple payers are involved, as well as our assessment that the costs of achieving precision in such transactions may far outweigh the benefits.

In the short-term, there are some adjustment-related activities that plans can control and, consistent with our authority in section 1860D-24(a)(1) of the Act, we can require that sponsors do these better. Therefore, we are proposing the following revisions to § 423.464:

- Revising paragraph (a) to clarify that all Part D sponsors must comply with administrative processes and requirements established by CMS to ensure effective coordination between Part D plans and other providers of prescription drug coverage for retroactive claims adjustments, underpayment reimbursements and overpayment recoveries; and
- Adding a paragraph (g)(7) to address the sponsors' responsibility to account for payments by SPAPs and other providers of prescription drug coverage in reconciling retroactive claims adjustments that create overpayments and/or underpayments, as well as to account for payments made, and for amounts being held for payment, by other individuals or entities. The new paragraph also specifies that Part D sponsors must have systems to track and report adjustment transactions and to demonstrate that—
 - ++ Adjustments involving payments by other plans and programs providing prescription drug coverage have been made;
 - ++ Reimbursements for excess cost-sharing and premiums for low-income subsidy eligible individuals have been processed in accordance with the requirements in § 423.800(c); and
 - ++ Recoveries of erroneous payments for enrollees have been sought as specified in § 423.464(f)(4).

13. Time Limits for Coordination of Benefits (§ 423.466)

Currently, there is no statutory or regulatory time limit for Part D sponsor coordination of benefits with SPAPs, other providers of prescription drug coverage, or other payers. Current CMS guidance as set forth in the Coordination of Benefits (COB) chapter of the Medicare Prescription Drug Benefit Manual requires Part D sponsors to establish at least a 90-day timely claims filing window and to make appropriate allowances for COB claims on a case-by-case basis. Section 50 of the COB chapter also requires sponsors, in retroactive enrollment situations, to coordinate benefits with other payers as required by the regulations at

§ 423.464(f), as well as accept claims from the beneficiary without imposing time limits. This section states further that sponsors, even in those situations when retroactive enrollment is not an issue, continue to be liable for claims received after the end of the coverage year as defined in § 423.308 and note that while contract provisions regarding timely claims filing may limit claims from network pharmacies, nonnetwork pharmacies and beneficiaries must still have the opportunity to submit claims for reimbursement without the imposition of time limits by the Part D sponsor.

Experience with Part D has shown there is benefit to be derived from placing a time limit on claims submission for Part D sponsor coordination of benefits. In addition to limiting sponsors' financial liability, a time limit would strengthen the ability of SPAPs, other providers of prescription drug coverage and other payers, including beneficiaries to obtain payment for covered Part D drugs. We would likewise benefit from a COB time limit by enabling us to close our Part D prescription drug databases.

In considering now establishing time limits on the submission of claims to Part D sponsors by beneficiaries and other payers of prescription drug coverage for proper coordination of benefits, we note that the Medicare FFS time limit for filing claims, as specified in § 424.44, is December 31st of the following year for services furnished during the first 9 months of a calendar year and December 31st of the second following year for services furnished during the last 3 months of the calendar year. The time for filing will be extended 6 months if the failure to file timely is due to an error or misrepresentation by an employee, intermediary, carrier, or agent of the Department. We also noted that States have a 3-year time limit for seeking recovery of Medicaid claims payments when the State is not the primary payer. Specifically, the Deficit Reduction Act of 2005 (Pub. L. 109-171) (DRA) strengthened the State Medicaid programs' ability to obtain payment from health insurers with which they need to coordinate benefits by adding section 1902(a)(25)(I) of the Act. The new section requires States to have laws in effect that require health insurers to make payment as long as the claim is submitted by the State within 3 years from the date on which the item or service was furnished. This DRA provision does not include SPAPs and, therefore, does not impose a time limit on the requirement for Part D sponsors to coordinate benefits with SPAPs.

Having considered these filing limit precedents, we now propose to establish a 3-year filing limit for Part D coordination of benefits with SPAPs, other entities providing prescription drug coverage, and all other payers, including beneficiaries or other individuals or entities paying, or holding amounts for payment, on the beneficiaries' behalf. Specifically, we propose to revise new § 423.466 by adding a new paragraph (b) that would establish a 3-year time limit on Part D coordination of benefits. That is, we propose to require Part D sponsors to coordinate benefits with SPAPs, other entities providing prescription drug coverage, and other payers for a period not to exceed 3 years from the date on which the prescription for the covered Part D drug was filled. By adding this provision to the regulation, we clarify timely filing responsibilities and deadlines for all beneficiaries and payers, as well as place a limit on Part D sponsors' claims payment liabilities and coordination of benefits responsibilities.

We are proposing this requirement consistent with our authority under sections 1860D-23(a)(2) and 1860D-24(a)(1) of the Act to establish requirements to ensure effective coordination among Part D plans, SPAPs, and other providers of prescription drug coverage, and consistent with our general rulemaking authority under section 1871(a) of the Act. Experience since the implementation of Part D has demonstrated that the ability of both CMS and the sponsors to manage our respective responsibilities in administering the program is complicated by the absence of any time limit for coordination of benefits. Part D sponsors face open-ended financial liability for continued benefit coordination and must project and include the costs of future liabilities in their bids. We also incur the expense of keeping our databases open to continue to accept prescription drug event data for the purpose of reopening Part D payment determinations to account for claims received by Part D sponsors from SPAPs, other entities providing prescription drug coverage, and other payers after the end of the coverage year. We believe that a 3-year limit provides more than ample time for beneficiaries to seek reimbursement of out-of-network and other paper claims, as well as sufficient time for coordination of benefits activities to take place among payers.

14. Use of Standardized Technology Under Part D (§ 423.120)

Section 1860D-4(b)(2)(A) of the Act, as codified in § 423.120(c), requires Part D sponsors to issue (and reissue, as appropriate) a card or other technology that may be used by an enrollee to assure access to negotiated prices under section 1860D-2(d) of the Act. Section 1860D-4(b)(2)(B) of the Act requires us to provide for the development, adoption, or recognition of standards relating to a standardized format for the card or other technology that are compatible with the administrative simplification requirements of Title XI of the Act and to consult with the NCPDP and other standard setting organizations, as appropriate. In accordance with section 1860D-4(b)(2)(B) of the Act, we consulted with NCPDP and subsequently issued guidance adopting NCPDP's "Pharmacy ID Card Standard", which is based on the American National Standards Institute (ANSI) INCITS 284-1997 standard entitled "Identification Card-Health Care Identification Cards", as the standard for identification cards for the Part D program. Information required in the Pharmacy ID Card Standard includes billing identifiers necessary to direct online real-time transactions to the appropriate online processor to enable real-time adjudication of the prescription drug claim at point of sale.

Our current regulations and guidance specifically address the requirement for Part D sponsors to issue (and reissue, as appropriate) standardized cards that may be used by an enrollee to ensure access to negotiated prices under section 1860D-2(d) of the Act. The only way that an enrollee can be assured access to the negotiated price at the point of sale is through online adjudication of the prescription drug claim. Any other price available to the beneficiary at the point of sale, as for instance, the pharmacy's "cash price", cannot be deemed to be the negotiated price mandated under section 1860D-2(d) of the Act. Therefore, to ensure access to these negotiated prices, the billing information on the cards must be used by the pharmacies at which beneficiaries fill their prescriptions to submit claims to an enrollee's Part D sponsor (or its intermediary). Beginning with the COB requirements originally issued on July 1, 2005, as required by section 1863D-23(a)(1) of the Act, and subsequently maintained as Chapter 14 of the Prescription Drug Plan Manual, we have instructed plan sponsors to process all claims online real-time (see section 50.4 entitled, "Processing Claims and Tracking TrOOP". The

requirements of accurate TrOOP accumulations, Part D benefit administration of multiple coverage intervals, and coordination of benefits with other payers all necessitate online real-time adjudication of individual pharmacy claims. Furthermore, since July 1, 2005, we have stated that we expect that Part D plan sponsors will establish policies and procedures appropriately restricting the use of paper claims to those situations in which on-line claims processing is not available to the beneficiary at the point of sale in order to promote accurate TrOOP accounting, as well as to minimize administrative costs to the Part D plans and the Medicare program and reduce opportunities for fraudulent duplicative claim reimbursements. We are now proposing at section 423.120(c)(3) to require Part D sponsors to contractually mandate that their network pharmacies submit claims electronically to the Part D sponsor or its intermediary on behalf of the beneficiary whenever feasible unless the enrollee expressly requests that a particular claim not be submitted to the Part D sponsor or its intermediary.

We are proposing to codify this guidance in regulation at this time because we have been made aware of an increasing number of instances in which network pharmacies are not submitting pharmacy claims to Part D Sponsors on behalf of Part D enrollees. Generally, we believe it is in the best interest of Part D enrollees to have their claims consistently processed through the Part D sponsor (or its intermediary). Not only does processing claims through the Part D sponsor ensure access to Part D negotiated prices, but it also ensures that proper concurrent drug utilization review (including safety checks) is performed (as required under 1860D-4(c) of the Act). Only the plan can conduct accurate concurrent drug utilization review when multiple pharmacies are utilized by the beneficiary or prevent payment to excluded providers. Online, real-time processing also facilitates accurate accounting for enrollees' true out-of-pocket (TrOOP) and total drug costs by the Part D sponsor so that each claim is processed in the appropriate phase of the benefit and accurate cost sharing assessed. In addition, a Part D sponsor cannot coordinate benefits with other payers as required under sections 1860D-23 and 1860D-24 of the Act if it never receives the claim.

We also propose to add a new paragraph (2) to § 423.120(c) to codify our existing guidance that Part D sponsors utilize standard electronic transactions established by 45 CFR

162.1102 for processing Part D claims. We will issue guidance on the use of optional or conditional fields in the HIPAA standard transactions through the Call Letter and Prescription Drug Benefit Manual instructions. We routinely work with NCPDP and industry representatives in arriving at recommendations for standardized use of such fields when necessary to improve administration of the Part D benefit. Previous examples of such guidance include those described in sections 50.4 and 50.5 of Chapter 14 of the Prescription Drug Benefit Manual on "Processing Claims and Tracking TrOOP" and "Standardized Claims Messaging", respectively. Such instructions are consistent with the rules governing use of HIPAA transactions whereby use of optional and conditional fields is governed by contractual terms between trading partners.

In a related matter, we are interested in better understanding the impact of a requirement for Part D sponsors to establish uniquely identifiable Part D payer/processor and enrollee identification numbers in billing and other coordination of benefits-related transactions. We have learned that not all processors organize their enrollment data this way, and some may rely upon other data such as person codes or dates of birth to distinguish between two enrollees (such as spouses) with a single identification number ("RxID"). This practice complicates coordination of benefits activities with other parties when unique identifiers are necessary. We have also learned that pharmacies cannot routinely distinguish Medicare Part D claims from other types of prescription drug coverage when the same routing information ("RxBIN and RxPCN") is used for all lines of business managed by a single processor. If pharmacies cannot consistently distinguish Part D claims, they cannot ensure that Part D claims and beneficiaries are handled in accordance with Part D-specific policies and procedures. Consequently we are proposing to add a new paragraph (c)(4) in § 423.120 to require that sponsors and their intermediary processors establish and exclusively utilize unique RxBIN or "RxBIN/RxPCN combinations" to identify all Medicare part D member claims, as well as to assign unique "RxID" identifiers to individual Part D beneficiaries. We solicit comments on the operational issues and timelines that would be involved in making these proposed technical changes to claims processing systems.

As stated previously, we generally believe it is in the best interest of Part

D enrollees to have their claims electronically submitted at the point of sale by pharmacies to the Part D sponsor (or its intermediary), but recognize there are situations when this will not be feasible or warranted. The most obvious example involves prescriptions filled at out-of-network pharmacies when Part D enrollees generally must pay out of pocket and submit paper claims for reimbursement from the Part D sponsor. Another example involves situations when network pharmacies offer special discount prices that are lower than plan negotiated prices. If this discounted price is not a pharmacy's usual and customary (U&C) price, we understand that the pharmacy may not offer it to the Part D sponsor (or its intermediary) for claims processing. In these situations, we have articulated a "lower cash price" policy whereby the enrollee may pay the pharmacy in full and submit a paper claim for reimbursement so that the costs will be counted towards his or her total drug spend and TrOOP balances. Finally, we also recognize that enrollees may have personal reasons for not wanting specific prescription claims processed through their Part D sponsor (or intermediary) and we uphold the enrollees' right to make such decisions. In situations such as the last two examples, our proposed requirement now clarifies that the enrollee must expressly request that a particular claim not be submitted to the Part D sponsor or its intermediary for processing. That is, the beneficiary should of his or her own initiative request that the claim not be submitted to the Part D plan, and this decision must neither be solicited nor assumed by the pharmacy.

While the previous examples explain why some pharmacy claims for Part D enrollees legitimately will not be processed through the Part D sponsor (or its intermediary), we are concerned about other reasons why network pharmacies may be failing to submit claims to Part D sponsors (or their intermediaries). Most notably, we are concerned that enrollees, their pharmacists or both incorrectly believe that the enrollee will always pay their Part D sponsor's higher negotiated price in situations when the pharmacy has a lower price. In many cases, this is illustrated by the enrollee submitting a paper claim after having paid cash at a network pharmacy even though the enrollee would have received the same price if the claim was processed through the Part D sponsor (or its intermediary) by the network pharmacy. We believe there may be confusion resulting from the increasing availability of very low

cost generic drugs at many Part D network pharmacies.

It is important to distinguish between a lower pharmacy price that is the pharmacy's U&C price versus a lower pharmacy price that is a non-U&C special discounted price. As our "lower cash price" policy describes, an enrollee would need to pay out of pocket and submit for reimbursement if the pharmacy's lower price is not its U&C price because the pharmacy will not submit that price to the Part D sponsor (or its intermediary). However, if the pharmacy submits a U&C price that is lower than a Part D sponsor's negotiated price, the enrollee will pay the lesser of the Part D sponsor's negotiated price or the pharmacy's U&C price. Therefore, the enrollee is better off when the pharmacy submits the claim to the Part D sponsor (or its intermediary) because the enrollee will pay the lower pharmacy price and have the dollar amounts reflected in their TrOOP and total drug spend balances.

Finally, we are concerned that sometimes enrollees are not aware that claims are not being processed through their Part D sponsor. We believe this can occur when pharmacies mistakenly believe that processing the claim through the Part D sponsor will result in the enrollee paying a higher Part D sponsor negotiated price or because the pharmacy deliberately does not want to incur transaction costs when the enrollee will be paying the pharmacy U&C price regardless. Our new requirement makes it clear that Part D sponsors must contractually require their network pharmacies to submit claims to the Part D sponsor (or its intermediary) whenever feasible unless the enrollee expressly requests that such claims not be submitted. We believe this requirement will help to ensure that Part D enrollees always have access to critical safety checks, as well as Part D negotiated prices and that their TrOOP and total drug spend balances accurately reflect their Part D expenditures.

15. Absence From Service Area for More Than 12 Months Under Part D (§ 423.44)

Section 1860D-1 of the Act establishes eligibility criteria for enrolling in a PDP plan or an MA-PD plan. In accordance with section 1860D-1(a)(3) of the Act, a "Part D eligible individual" is defined as an individual who is entitled to or enrolled in Medicare benefits under Part A or enrolled in Part B. In order to enroll in a PDP, the individual must reside in the plan's service area, and cannot be enrolled in an MA plan, other than an MSA plan or PFFS plan that does not

provide qualified prescription drug coverage.

Section 1860D–1(b)(1)(B) of the Act generally directs us to use disenrollment rules similar to those established under section 1851 of the Act. We applied the provisions of section 1851(g)(3) of the Act that provide authority for the basis of terminations for MA plans, which are codified in § 422.74. The disenrollment provisions for PDPs are outlined in § 423.44.

Under the current MA and PDP rules at § 422.74 and § 423.44, respectively, individuals who are out of the service area for more than 6 months will be disenrolled. There is an exception for MA plans that offer visitor or traveler benefits which allows a temporary absence from the service area for up to 12 months. However, given the inherent difference between PDPs and MA plans (in particular, the range of services each provides) we believe that it may not be appropriate or necessary to apply the disenrollment requirements established under MA in the same way for PDPs. The 6-month limit on the length of time an MA enrollee may be out of the service area before being disenrolled is based in large part on the inability of the enrollee to access the full range of medical services while out of the plan service area. However, Part D benefits generally can be accessed through a national pharmacy network, which can serve individuals effectively regardless of whether they are in their PDP region of residence. Thus, the same out-of-area time limit for PDPs may not be necessary, as long as there are specific assurances from the PDP that individuals will have access to PDP benefits while out of the area (provided the individual remains in the United States). For example, a PDP may have shared computer systems with PDPs in other regions or have a network of pharmacies in other regions (or nationwide) that would provide immediate access to prescription drugs outside of the region on the same basis as pharmacies within the enrollee's region of residence.

Therefore, given the nature of the Part D benefit and the strong likelihood that a PDP enrollee can access the full range of PDP benefits while out of the service area, we are proposing to amend § 423.44 to allow a temporary absence from the PDP plan service area for up to 12 months before disenrollment would be mandatory. We believe 12 months is an appropriate time frame because it is consistent with the time frame for MA plans' visitor or traveler benefits.

16. Prohibition of Mid-Year Mass Enrollment Changes by SPAPs Under Part D (§ 423.464(e))

Section 1860D–23(b) of the Act defines a SPAP as a State program that (1) provides financial assistance for the purchase or provision of supplemental prescription drug coverage or benefits on behalf of part D eligible individuals; (2) when determining eligibility and the amount of assistance to Part D eligible individuals under the Part D program, provides assistance to such individuals in all Part D plans and does not discriminate based upon the Part D plan in which the individual is enrolled; and (3) satisfies the requirements of other provisions in section 1860D–23 of the Act, like Medicare as primary payer. Section 1860D–23(a)(1) of the Act provides that the Secretary has the authority to establish requirements for Part D sponsors to ensure the effective coordination between a Part D plan and an SPAP. Included among those requirements are enrollment file sharing, claims processing and payment, claims reconciliation, application of the out-of-pocket expenditures, and other administrative processes set by the Secretary. In order to coordinate effectively with Part D sponsors, we permit SPAPs to conduct large volumes of enrollments (sometimes referred to as "mass enrollments") consistent with our nondiscrimination guidance (see Chapter 14 of the Medicare Prescription Drug Benefit Program Manual). Most SPAPs perform these mass enrollments on a calendar year basis for all its members who have not chosen a Part D plan; however, some SPAPs have chosen to perform these enrollments on a noncalendar year basis. In these situations, Part D sponsors have found that substantial disenrollment of large numbers of SPAP members from one plan, followed by mass enrollment into another during the calendar year significantly affects their financial operations.

We believe that mass re-enrollment into a new plan mid-year disrupts any continuity of care the beneficiary has established with his other current Part D plan, and introduces transition risks such as drugs not being covered by the member's new plan, or requiring the member to change his or her pharmacy that are not outweighed by any administrative convenience to the SPAP. Therefore, given these concerns, we are proposing, under our authority described above, to add a requirement to § 423.464(e) to prohibit mid-year mass enrollment changes by SPAPs. We believe this revision would deter any SPAPs from engaging in what has been

a rare but exceedingly disruptive practice, and require large enrollment changes to be made on a calendar year basis only. We note that individual members of qualified SPAPs (or the State acting as the authorized representative of individual members) will continue to have Special Enrollment Periods (SEP), as provided in the current CMS guidance, for case-by-case enrollment actions.

In addition to beneficiary disruptions, our actuaries have determined that there are significant financial disparities among the Part D plans related to mass mid-year plan enrollment changes. The source of the disparity is the front-loading of plan liabilities in the annual bid due to the unique benefit structure of Part D program, including the coverage gap. Specifically, plans that have beneficiaries early in the year are likely to incur expenses attributable to the initial coverage period, the portion of the benefit that includes 75 percent coverage. Plans that have beneficiaries later in the year are more likely to have beneficiaries during the coverage gap portion of the benefit, which requires 100 percent beneficiary cost-sharing and no plan payment obligation in most cases. Because the funding of the benefit is uniform over the entire plan year, plans that lose beneficiaries mid-year are more likely to incur losses (the premiums associated with these beneficiaries after the initial coverage period), and plans that acquire beneficiaries mid-year from other Part D plans are more likely to experience gains (due to the beneficiaries enrolling during the gap in coverage) that in neither case have been anticipated in the plan's bids. This inequitable result demonstrates the importance of having a policy in place that minimizes mass mid-year plan changes.

17. Nonrenewal Beneficiary Notification Requirement Under Parts C and D (§ 422.506, and § 423.507)

Section 1857(a) of the Act provides the Secretary with the authority to enter into contracts with MA organizations, and section 1860D–12(b)(1) of the Act provides the Secretary with the authority to enter into contracts with PDP sponsors. Additionally, sections 1857(c)(1) and 1860D–12(b)(3)(B) of the Act grant the Secretary the authority to renew contracts. In accordance with the above-referenced authority, we have issued contracting regulations including § 422.506 of the MA regulations, and § 423.507 of the Part D regulations which provide for the nonrenewal of a contract.

Nonrenewals of MA or PDP contracts require the MA organization, the Part D

sponsor, or CMS to notify both the enrollees of the organization or sponsor and the general public of the nonrenewal. Existing regulations require notification 60 days prior to the effective date of the nonrenewal for notification both to enrollees and to the general public. The effective date of contract nonrenewals in the MA and PDP programs is January 1st of each calendar year. We propose to change the requirement for notification to enrollees from an "at least 60 day requirement" to an "at least 90 day requirement", as it was prior to January 1, 2009.

Changing the requirement for the personalized beneficiary specific CMS-approved notice to at least 90 days provides beneficiaries with an increased notice period giving beneficiaries more time to choose a new Medicare plan prior to the start of the new benefit year. When we changed the required notice period to 60 days, we did so primarily to provide adequate time for the appeals process to conclude prior to the start of the next calendar year; however, our recent experience has indicated that the vast number of nonrenewals are voluntarily elected by the PDP sponsor or MA organization, so there is rarely a need to accommodate the appeals process. For this reason, we propose revising § 422.506(a)(2)(ii) and (b)(2)(ii) of the MA regulations and § 423.507(a)(2)(ii) and (b)(2)(ii) of the Part D regulations to change the beneficiary notice requirement from at least 60 days to at least 90 days.

We also propose removing the current requirement for nonrenewing plans (in voluntary nonrenewal situations) and for us (in CMS-initiated nonrenewal situations) to provide notice to the general public by publishing a notice in one or more newspapers of general circulation concerning the impending nonrenewal. This change is motivated by the cost of newspaper advertisements and the declining rate of newspaper circulation, weighed against the very limited benefit gained from notice to the general public who is minimally, if at all, affected by the nonrenewal. Also, non-renewal information is now easily available to the general public through Internet web sites maintained by us (for example, <http://www.Medicare.gov>), a resource not available to the public when the newspaper notice requirement was first adopted. We believe that the requirement to provide personalized nonrenewal information to plan enrollees is sufficient to ensure adequate nonrenewal notice to the beneficiaries that are being nonrenewed, the population that is most directly affected by the nonrenewal. For this

reason, we propose deleting § 422.506(a)(2)(iii) and (b)(2)(iii) of the MA regulations and § 423.507(a)(2)(iii) and (b)(2)(iii) of the Part D regulations to remove the requirement that the general public be informed of the impending nonrenewal through the publication of newspaper notices.

18. Notice of Alternative Medicare Plans Available To Replace Nonrenewing Plans Under Parts C and D (§ 422.506(a)(2)(ii) and § 423.507(a)(2)(ii))

To allow additional operational flexibility, we also propose to change the requirement for PDP sponsors and MA organizations to provide written notification of the alternative Medicare plans available to replace the nonrenewing plan. We propose changing the requirement to include the option of either providing a written list of alternatives available, or placing outbound calls to all affected enrollees to ensure beneficiaries know whom to contact to learn about their enrollment options. We believe this change will be advantageous for beneficiaries because, depending on where the beneficiary resides, a listing of available plan options is often very long and may be too overwhelming for the beneficiary to use appropriately. A much more useful approach would be to provide beneficiaries with contact information and resources for identifying the most appropriate option given their unique, individual circumstances. For this reason, we propose revising § 422.506(a)(2)(ii) of the MA regulations and § 423.507(a)(2)(ii) of the Part D regulations, to provide the option of sending written notices of all available alternatives or placing outbound beneficiary calls to ensure beneficiaries know whom to contact to learn about their enrollment options. In either case, as discussed earlier in this section, a personalized CMS-approved beneficiary notice regarding the nonrenewal still must be sent to each beneficiary.

19. Timeframes and Responsibility for Making Redeterminations Under Part D (§ 423.590)

In accordance with section 1860D-4(g) of the Act, the Part D redetermination notice provisions in § 423.590 largely mirror the MA reconsideration notice provisions in § 422.590. There is one notable exception—§ 422.590(d)(3) allows MA plans to make the initial notice of a completely favorable expedited reconsideration orally, so long as a written confirmation is mailed to the enrollee within 3 calendar days of the oral notice. We did not carry over this

requirement to § 423.590, although a parallel instruction is contained in our subregulatory guidance in Chapter 18 of the PDP manual. Therefore, we propose to reconcile this discrepancy by adding new § 423.590(d)(2). Consistent with the requirements in § 422.590(d)(3), new § 423.590(d)(2) will allow Part D plan sponsors to make the initial notice of a completely favorable expedited redetermination orally, so long as a written confirmation of the fully favorable decision is mailed to the enrollee within three calendar days of the oral notice.

We also propose in § 423.590(d)(2) to allow Part D plan sponsors to make the initial notice of an adverse expedited reconsideration orally, so long as a written confirmation of the decision is mailed to the enrollee within three calendar days of the oral notice. We also propose to add a cross reference to paragraphs § 422.590(d)(1) and (d)(2) in paragraph (g) in order to apply the written notice requirements in paragraph (g) to adverse expedited redetermination decisions. We recognize that the MA reconsideration notice provisions at § 422.590(d)(5) and (e) do not provide explicit instructions regarding how MA organizations are to notify MA enrollees of adverse expedited reconsideration decisions. However, given the expedited status of these requests, we believe adding these two proposed notice requirements to the Part D expedited redetermination process is in the enrollee's best interests. Additionally, because adverse redetermination decisions are not automatically forwarded to the Part D Independent Review Entity, Part D enrollees need to receive clear information about the right to appeal and the procedures for appealing. We note that these two proposals are consistent with our subregulatory guidance and the process for notifying enrollees of expedited adverse coverage determination decisions in § 423.572(b).

Similarly, § 423.590(a)(1) requires a plan sponsor to send an enrollee written notice of a completely favorable decision for benefits; however, the regulations do not specify the content of that notice. Consistent with the statute, § 423.590(a)(1) mirrors the parallel provision at § 422.590(a)(1). However, for the same reasons outlined in the discussion above in this section, we believe incorporating notice requirements for the Part D standard reconsideration notice provisions does not conflict with the related MA provisions, and will provide an important beneficiary protection that will ensure continuity of care for Medicare beneficiaries who are

obtaining refills of prescription drugs under Part D. Therefore, we propose to add § 423.590(h) to establish the form and content requirements for completely favorable redetermination decisions, and propose making those notice requirements applicable to redeterminations issued under paragraph (a)(1). We also propose to reference paragraphs (d)(1) and (d)(2) in paragraph (h), so the proposed form and notice requirements in paragraph (h) will apply to completely favorable expedited redetermination decisions.

20. Requirements for Requesting Organization Determinations Under Part C (§ 422.568)

Section 1852(g)(3) of the Act allows an enrollee to request an expedited organization determination either orally or in writing. However, the method for requesting a standard determination is not addressed in either the Act or the implementing regulations at § 422.568. Both beneficiary advocates and MA plans have voiced concern about the absence of express regulatory authority allowing enrollees to request standard organization determinations both orally and in writing. Therefore, we propose adding specific language in § 422.568 allowing oral requests for organization determinations, except where the request is for payment.

21. Organization Determinations Under Part C (§ 422.566 and § 422.568)

Section 1852(g)(1)(A) of the Act requires MA organizations to have a procedure for making determinations regarding whether an enrollee is entitled to receive health services or payment under the program. In accordance with section 1852(g)(1)(A) of the Act, § 422.566 and § 422.568 establish the requirements related to organization determinations and notices. Existing § 422.566(b)(4) specifies that an organization determination includes a determination resulting in “[d]iscontinuation or reduction of a service *if* the enrollee believes that continuation of the services is medically necessary.” (emphasis added). Similarly, under § 422.568(c), the plan must give the enrollee a written notice of the determination “*if* an enrollee disagrees with the MA organization’s decision to discontinue or reduce an ongoing course of treatment.” (emphasis added).

Both of these provisions have at times been read to imply that the existence of an organization determination, and the associated notice requirements, were tied to the enrollee’s “belief” or “disagreement.” Therefore, we propose changing this language to better reflect

its meaning and purpose by removing the phrases “if the enrollee believes that continuation of the services is medically necessary” and “if an enrollee disagrees with an MA organization’s decision to”. Regardless of an enrollee’s decision whether to appeal as a result of this discontinuation or reduction, the key purpose of these provisions was to ensure that enrollees received an explanation of the plan’s decision and their rights if they choose to appeal the determination. Therefore, we propose removing the language noted above from § 422.566(b)(4) and § 422.568(c).

22. Representatives (§ 422.561, § 422.574, and § 422.624)

For various reasons, enrollees may choose or need to have someone represent them in the appeals process in order to protect their interests. Presently, under sections 1852(f) and (g) of the Act, a representative may act on behalf of an enrollee or other party when filing a grievance. However, existing § 422.561 does not explicitly permit the filing of grievances by representatives unlike the corresponding Part D regulation. In order to rectify this and be consistent with the Part D definition of representative at § 423.560, we propose to amend § 422.561 to clarify that a representative may act on an enrollee’s behalf with respect to the grievance process.

23. Disclosure Requirements Under Parts C and D (§ 422.111(g) and § 423.128(f))

Section 1857(a) of the Act provides the Secretary with the authority to enter into contracts with MA organizations, and section 1860D–12(b)(1) of the Act provides the Secretary with the authority to enter into contracts with PDP sponsors. Currently, § 422.111 and § 423.128 provide specific requirements on information that must be disclosed to enrollees, either at specific designated times, or upon request. We are proposing at § 422.111(g) and § 423.128(f) to state that we may require a sponsoring organization to disclose to its enrollees and potential enrollees information concerning the sponsoring organization’s performance and contract compliance deficiencies in a manner specified by CMS. This disclosure may be required when a sponsoring organization is sanctioned, or when a sponsoring organization’s compliance and/or performance deficiencies rise to a certain level, such that we determine it is necessary for the sponsoring organization to notify its existing and potential enrollees of these deficiencies. The vehicle by which the information is

disclosed by the plan, such as through the organization’s Web site, pre-enrollment materials, or separate letter to enrollees, and the timing and content of that disclosure, are subject to CMS review and approval. The language we are proposing is not intended to limit these required disclosures to particular times of the year when beneficiaries would ordinarily be able to make changes or elections (for example, AEP or OEP). We believe that this kind of transparency will provide additional incentives for sponsoring organizations to make improvements to their operations and also provide relevant information to beneficiaries and the public concerning plan choices. We solicit comment on these regulatory provisions. In particular, we solicit comment on whether these disclosure requirements should be imposed only in those circumstances where a beneficiary would be afforded the opportunity to act on them (for example, requiring disclosure during the particular times of year when beneficiaries would ordinarily be able to make change or elections, except in those situations where the compliance deficiency is so significant that a beneficiary may be afforded a special enrollment opportunity).

24. Definition of MA Plan Service Area (§ 422.2)

Section 1851(b)(1)(A) of the Act provides that Medicare beneficiaries are eligible to enroll in an MA plan only if they reside in the geographic area served by the MA plan, that is, the “service area.” An MA plan’s “service area” is currently defined in § 422.2 and the definition expressly requires organizations to meet access standards, in accordance with access standards in § 422.112.

One question that has been posed to us is whether incarcerated individuals are eligible to join an MA plan, especially an MA plan that does not offer Medicare prescription drug coverage. Note that the definition of service area for a Part D plan (§ 423.4) already excludes a jail or prison within the boundaries of the Part D plan service area, given that beneficiaries in jail or prison do not have access to pharmacies as required under § 423.120. It is a logical conclusion that incarcerated beneficiaries similarly would not have access to MA plan services, as required under § 422.112. Therefore, such an area could not meet the MA service area definition, which requires that such access standards be satisfied. Additionally, there is no reason for an individual to enroll in an MA plan while incarcerated, since basic health

care services typically are furnished by the jail or prison. Similarly, it would not be appropriate for an MA organization to receive monthly payments for such an individual, since medical services typically would be covered for the individual by the facility in which the individual is incarcerated. Such payments would represent an unwarranted windfall for services the MA organization would not have to, and could not, deliver. Therefore, we are proposing to amend the definition of an MA plan "service area" at § 422.2 to exclude facilities in which individuals are incarcerated.

C. Changes To Provide Plan Offerings With Meaningful Differences

This section addresses proposed changes to our regulations designed to foster plan offerings with meaningful differences. One of the underlying principles in the establishment of the Medicare Part D prescription drug benefit and the revisions to the Medicare managed care program resulting from the MMA was that both market competition and the flexibility provided to MA organizations and Part D sponsors in the statute would result in the offering of a broad array of cost-effective health and prescription drug coverage options for Medicare beneficiaries. Indeed, in the several years since implementation of the MMA, private health plans have taken full advantage of the opportunity to offer a wide array of health care plans and prescription drug benefit packages to Medicare beneficiaries. As a result, since 2006, Medicare beneficiaries throughout the United States have had available to them a multiplicity of health care and prescription drug options offered by a substantial number of private sector entities. We continue to support the concept of offering a wide variety of health plan and prescription drug coverage choices for Medicare beneficiaries consistent with our commitment to afford beneficiaries access to high value health care. However, based on several years of experience with the MA and Part D programs, we have learned that although beneficiaries need access to a variety of alternative plan options, benefit packages must represent significant differences to ensure meaningful choices. As noted previously, we have attempted to work with Part D sponsors since 2006 to

reduce the number of offerings from PDP sponsors as well as to convey information about Part D plan benefit designs in ways that are meaningful and understandable to beneficiaries. For example, we provide information about the various local MA plan and PDP options available to beneficiaries in the health plan charts included in the annual Medicare & You publication. Because there are practical limitations to the display of detailed comparative information in a print format, we also provide comparative plan information through other vehicles. We post landscape files to our Web site ([see http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/](http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/)) that provide more detailed comparative information, such as information about benefit type and, for Part D, whether the plan has a \$0 premium with full LIS subsidy, and a description of any gap coverage provided. This information is geared more toward beneficiary advocates and researchers than beneficiaries.

In addition, because a static description of plan benefits design features does not suffice to allow meaningful comparisons between drug plans, we also design and maintain the Medicare Options Compare (MOC) and the Medicare Prescription Drug Plan Finder (MPDPF) Web tool. These Web tools allow beneficiaries to customize their comparisons based on their particular needs and thus compare plan benefit packages in a meaningful way. For example, the MPDPF allows beneficiaries or their representatives to develop customized comparisons that are sensitive to a beneficiary's drug regimen, as well as tolerance for generic and therapeutic substitutes. Our goal in maintaining this tool is to strike a balance between the desire to provide as much information as possible to beneficiaries yet only provide information that is useful in making appropriate drug plan choices. We continue to look for ways to improve this tool and make information more understandable to beneficiaries and welcome comments in this area. Ensuring that Part C and D sponsors offer substantially different plan options, as the proposed regulatory changes discussed below are intended to do, will further maximize opportunities for beneficiaries to select benefit packages that meet their particular needs, while also

streamlining and simplifying the plan selection process.

Half of all Medicare beneficiaries have over 40 MA plan choices (this figure does not include special needs plans or employer group health plans which have additional criteria for enrollment), and many states offer 50 or more stand alone Part D plans, a number that can double when one includes Medicare Advantage plans with a Part D benefit. Several studies suggest that the MA and Part D program offerings are so numerous that they can be confusing. In a report by Marsha Gold of Mathematica Policy Research, Inc., for example, Gold writes of the MA program that "Existing research suggests that simplification may have advantages for beneficiaries," and that one such advantage is preventing competitors to take advantage of the system "through product design."⁵ In his study, "How Much Choice is Too Much? The Case of the Medicare Prescription Drug Benefit," T. Rice argues, based on Part D beneficiary studies that he and others in the field have conducted, that "The results show that decision quality [of seniors' ability to choose plans with the lowest annual total cost] deteriorated as the number of plans increases."⁶

As part of our goal of streamlining and simplifying the plan selection process for beneficiaries, we are also proposing to revise the nonrenewal regulations to expressly provide as a ground for nonrenewal the fact that an MA or Part D plan has failed to attract more than a small number of enrollees over a sustained period of time. In deciding whether to nonrenew a plan on this basis, we would expect to consider arguments as to why such low enrollment would be defensible in a particular situation (for example, the plan provides a benefit structure that is extremely important to its enrollees, despite the fact that they are small in number).

In this section, we discuss our proposed revisions to both the bid submission and review processes and the nonrenewal regulations. We believe these proposed revisions will help us accomplish the balance we wish to strike with respect to encouraging competition and providing health plan and PDP choices to beneficiaries that represent meaningful choices in benefit packages. Table 3 outlines these proposed revisions.

⁵Gold, Marsha. Strategies for Simplifying the Medicare Advantage Market. Publication prepared for the Kaiser Family Foundation. July, 2009.

⁶Rice, T. Reducing the Number of Drug Plans for Seniors: A Proposal and Analysis of three Case

Studies. Presentation at Academy of Health Annual Research Meeting: Washington, DC. June 9, 2008.

TABLE 3—PROVISIONS TO ENSURE MEANINGFUL DIFFERENCES IN PLAN OFFERINGS

Provision	Part 422		Part 423	
	Subpart	Section	Subpart	Section
Bid Submissions: Ensuring Significant Differences	Subpart F ...	§ 422.254	Subpart F ...	§ 423.265.
Bid Review Process	Subpart F ...	§ 422.256	Subpart F ...	§ 423.272.
Transition Process in Cases of Acquisitions and Mergers).	Subpart F ...	§ 422.256	Subpart F ...	§ 423.272.
Non-renewing Low-enrollment Plans	Subpart K ..	§ 422.506(b)(1)(iv)	Subpart K ..	§ 423.507(b)(1)(iii).

1. Bid Submissions—Ensuring Significant Differences (§ 422.254 and § 423.265)

Consistent with our authority under section 1857(e)(1) of the Act, incorporated for Part D by section 1860D–12(b)(3)(D) of the Act, to establish additional contract terms and our authority under section 1860D–11(d)(2)(B) of the Act to propose regulations imposing “reasonable minimum standards” on Part D sponsors, we propose to amend § 422.254(a)(4) and § 423.265(b) to specify that, when submitting bids to contract as an MA organization or Part D plan sponsor for the following contract year, MAOs and Part D sponsors must ensure that they submit bids for multiple plans in the same area only if those plans have significant differences from each other in terms of key benefit or plan characteristics such as premiums, cost-sharing, formulary structure, or benefits offered.

By proposing this change to our existing regulatory requirements regarding submission, review, and negotiation of bids, as well as CMS approval of plans, we aim to strengthen and build on our efforts to date to ensure a proper balance between affording beneficiaries a wide range of plan choices and avoiding undue beneficiary confusion in making coverage selections. Since 2005, we have reviewed Part D plan bids and negotiated with sponsors based on key benefit package characteristics, such as deductibles, substantial formulary differences, coverage in the coverage gap, and previous enrollment numbers. We also have reviewed plan offerings and negotiated with Part C contractors as part of our annual bid review and approval process, in an effort to identify and eliminate MA plans that appear to be duplicative. In connection with 2010 plan offerings, for example, we contacted MAOs whose plans in a service area represented insignificant cost differences, as well as MAOs having MA plans with 100 or fewer enrollees, and conveyed our expectation that they consolidate or terminate such plans, when appropriate.

We do not propose to specify in regulations text specific benefit package requirements or enrollment thresholds. Rather, it is our goal to permit MA organizations and PDP sponsors maximum flexibility to create plans with meaningful differences and, where warranted, to permit low enrollment plans to continue to operate when it is in the best interest of the program and of Medicare beneficiaries. We would issue guidance about the overall process, including the criteria for meaningful plan offerings and assessment of such offerings, in the annual Part C and D Call Letter. With this in mind, with respect to Part C, we would consider meaningful differences among plans offered by an MAO in a service area, as determined by CMS, to include a mix of plan types (for example, HMO, PPO, private FFS, or MSA plan), significant differences in plan benefit packages (the offering of a Part D benefit or a significant Part B buy-down, for example), or significant differences in premiums or cost-sharing (for example, a low premium-high cost-sharing plan versus a high premium-low cost-sharing plan) or aggregate costs to beneficiaries. In one possible scenario, under these general guidelines, we would particularly scrutinize whether there were sufficient differences among MA plan options if an MAO proposes to offer more than two plans of the same plan type in a service area. Even if only two plans of a given type are offered, they would, under our proposal, have to have meaningful differences relative to one another. For example, if two MA plans included a Part D benefit, we would require that there also be significant differences between these plans’ Part D benefits in terms of premiums, cost-sharing or other benefits.

If the proposed new requirement is implemented, we would require that plans be dropped that do not offer meaningful choices for beneficiaries. In making determinations about what is a meaningful choice of plan type, we could view a PPO and an HMO with a POS benefit as being similar plan offering if the POS benefit covered all A

and B services out of network. Similarly, a network private FFS plan and a PPO plan could also be viewed as similar plan offerings given the similarity in the access to services rules between these two MA plan types.

With respect to Part D plans, we would continue to focus our analysis on whether there are significant differences in proposed beneficiary out-of-pocket costs as a result of the deductible amounts (for example, \$0 deductible versus a \$310 deductible) and cost share or coinsurance (for example, a \$20 cost share versus a \$45 cost share for preferred brand drugs). We also would evaluate plan formularies (for example, a 25 percent difference in the number of unique generic entities offered on the plans’ formularies). These factors are the most significant considerations that are applicable to all benefit types. We solicit comment on how big the differences between plan offerings need to be in order to be “meaningful” to beneficiaries. For example, is there a meaningful difference between an enhanced plan with a \$0 deductible and no coverage in the gap versus an enhanced plan with a \$0 deductible and coverage of 50 generic drugs in the gap?

Additional benefit offerings such as free first fill programs and brand-name only deductibles may also be considered for the appropriate benefit types. In addition to the current considerations of formulary depth and breadth we may also consider the overall percent of utilization management applied to drugs and the specific types of utilization management (for example, prior authorization and step therapy). It is important to note that, even though a sponsor may submit different formularies for different plan offerings, all submitted formularies must be sufficiently robust to pass our rigorous formulary reviews and be determined not to discourage enrollment by certain types of beneficiaries. Based on our experience and given statutory actuarial equivalency requirements, we do not expect that, absent substantial differences in approved formularies, sponsors can demonstrate substantial differences between plans offering basic

prescription drug coverage. It is also our experience that sponsors typically must offer substantial coverage in the coverage gap as a supplemental benefit in order to demonstrate that one enhanced alternative plan design is substantially different from another.

We are proposing that, in our review process, we would provide particular scrutiny in those market areas where multiple MAOs or Part D sponsors offer multiple plans. Specifically, we would particularly target our resources to our review for “meaningful differences” in areas where the elimination of duplicative plans would still leave a large number of plan options. For example, in the highly competitive Miami-Dade county market area, we might particularly focus our review on multiple HMO offerings from the same MAO in areas where additional HMO plans are not adding meaningful new choices for prospective enrollees. Similarly, we would particularly scrutinize Part D plan offerings from the same Part D sponsors for meaningful differences in regions where multiple plans with multiple benefit types (for example, enhanced alternative coverage, coverage in the gap) already exist.

As we continue to accumulate program experience negotiating with MA organizations and Part D plan sponsors regarding bid submissions, it is our intent to apply these “lessons learned” both to our bid submission requirements and to our bid negotiation protocols. We expect to continue to determine whether there are substantial differences in plan types and benefit packages by looking at factors such as health plan benefit packages, cost-sharing, and deductibles, substantial formulary differences, and coverage in the coverage gap. We are soliciting comments on our proposed changes to the bid submission process.

As discussed more fully in section II.B.5. of this proposed rule, we are also interested in building additional checks into our process to ensure that, in structuring bids that are sufficiently different from any other bid they may propose, MAOs and Part D sponsors do not design benefit packages that have the effect of discriminating against certain types of Medicare beneficiaries. This is consistent with our statutory authority in sections 1852(d)(1)(A) and 1860D–11(e)(2)(D)(i) of the Act, which provide that we may disapprove a bid if we find that a plan’s proposed benefit design substantially discourages enrollment in that plan by certain Medicare-eligible individuals.

In the context of the MA program, we are especially concerned about cost-sharing for certain high-cost services

and would caution plans to ensure that when crafting plan packages with meaningful differences, they do not create discriminatory cost-sharing structures. We have the authority, under section 1852(b)(1) of the Act (implemented at § 422.110), to reject bids that we determine to be discriminatory. With respect to Part D sponsors, a plan that is considering an additional benefit package that is both nondiscriminatory and substantially different from its basic or enhanced alternative PDP offering(s) might choose to bid on enhanced alternative coverage that includes coverage of both some brand and generic drugs in the coverage gap. Depending on how this enhanced alternative coverage were structured, such a design could meet the threshold of being substantially different from a benefit package offering basic prescription drug coverage and/or an enhanced alternative benefit package that only offers coverage of certain excluded drugs, as provided in § 423.104(f)(1)(ii)(A).

2. Bid Review Process (§ 422.256 and § 423.272)

In order to further ensure that the benefit packages and plan cost structures offered by an MAO or Part D sponsor are meaningfully different, consistent with the preceding discussion, we propose to add § 422.256(b)(4)(i) and § 423.272(b)(3)(i) to provide that we will only approve a bid submitted by an MAO or Part D sponsor if we find its plan benefit package to be substantially different from the plan benefit packages reflected in that sponsor’s other submitted bids in terms of key plan characteristics such as premiums, cost-sharing, formulary structure, or benefits offered.

3. Transition Process in Cases of Acquisitions and Mergers (§ 422.256 and § 423.272)

Based on several years of program operational experience, we have also learned that when an MAO or Part D sponsor (or a parent organization to the sponsor) purchases another MAO or PDP sponsor, the result can be that the single parent organization offers plans through multiple subsidiaries of that same parent that are not substantially different from one another. In this specific situation, plan options may be designed by a subsidiary that has no incentive to compete against plans offered by other subsidiaries, which may result in multiple plan offerings by one sponsor or parent organization that do not represent substantial or truly meaningful choices to beneficiaries.

In the 2008 Call Letter for Medicare health plans and PDPs, we announced a policy under which PDP sponsors or parent organizations with new acquisitions would be afforded a period of 3 years to transition their plan offerings to meet the goal of ensuring that the sponsor’s offerings were substantially different from one another. For example, a PDP sponsor (or its parent organization) completing an acquisition of another sponsor in November 2009 would not be subject to requirements for offering substantially different bids until the 2013 contract year (that is, bids would be due in June 2010 for the 2011 program year; transition would occur during 2011 and 2012; and the plan sponsor or parent would need to ensure that in June 2012, when it submits its bids for program year 2013, all of its 2013 bids are for substantially different plans).

Consistent with existing policy, we propose adding a new paragraph § 423.272(b)(3)(ii) providing for a 2-year transition period in the case of a merger of Part D plan sponsors or the acquisition of a Part D plan by another Part D plan sponsor or parent organization. We believe a 2-year transition period strikes a balance between allowing sponsors (or their parent organizations) with recent acquisitions sufficient time to streamline their operations after completion of an acquisition with the need to streamline and simplify beneficiary plan selection. We are proposing the 2-year transition instead of our current policy of 3 years based on our experience with Part D sponsors that have merged with or acquired other sponsors. Based on our experience, we believe that a 2-year period permits sponsors ample time to ensure that all plans offered represent significant differences, especially because, as indicated in the sample bidding cycle outlined above, we do not count the year of the merger or acquisition as part of the 2-year period.

After a transition period of 2 years, we would only approve a bid submitted by a PDP sponsor, or a parent organization to that PDP sponsor, if the benefits or plan cost structure represented by that bid was substantially different from any other bid submitted by the same Part D sponsor (or parent organization to that Part D sponsor) in terms of key plan characteristics, such as premiums, cost-sharing, or formulary structure.

We are also proposing to make a similar change so that MA plans acquired through purchase or merger offered by same MAO or parent organization reflect meaningful differences after a 2-year transition

period. We propose to codify this policy at § 422.256(b)(4)(ii).

We request comments regarding the adequacy of our proposed transition period length of 2 years in both the MA and Part D contexts.

4. Non-Renewing Low-Enrollment Plans (§ 422.506(b)(1)(iv) and § 423.507(b)(1)(iii))

We are proposing to revise the Part C and Part D nonrenewal regulations to include, as a specific ground for nonrenewal, a finding that a plan has failed to attract a significant number of enrollees over a sustained period of time. We believe that, absent special circumstances, which we discuss below, a plan that has failed, over a sustained period, to attract enrollees is being operated in a manner “inconsistent with the efficient and effective administration” of the Part C or Part D programs, within the meaning of section 1857(c)(2)(B) of the Act, which is incorporated into Part D by section 1860D–12(b)(3)(B) of the Act, and thus would be subject to termination.

In the 2010 Call Letter, we announced that MA organizations and PDP sponsors should terminate or consolidate low-enrollment Part C and D plans. In advance of the 2010 contract year, we have contacted MAO sponsors with enrollments of 100 beneficiaries or fewer for 2 or more years, conveying our expectation that the organization consolidate or terminate such plans. We

now propose to add continuously low enrollment to the specific regulatory grounds for nonrenewal by CMS of an MA plan or PDP. We note that this requirement would be independent of the current requirement in § 422.514(a) and § 423.512(a) that MAOs and Part D sponsors meet minimum enrollment requirements at the organization level for purposes of entering into a contract with us. Those requirements apply to all enrollees of the organization, not enrollees in a particular plan.

Although low enrollments often reflect lack of beneficiary interest in a plan, there are instances when low enrollment is a function of the type of beneficiaries served, geographic location, or other circumstance. Instances in which we would consider a waiver of the proposed requirements include but are not limited to a chronic care SNP offering health care services especially tailored to this category of beneficiaries not available elsewhere, or an employer group health plan offering benefits augmenting those of an MA plan to employees of a small business. If a case can be made that low enrollment is justified and the absence of such a plan would significantly limit beneficiary health care options in a service area, consistent with effective and efficient administration of the Part C or Part D benefit, we would not nonrenew that plan. Similarly, although we believe an enrollment of 100 or fewer beneficiaries for 2 or more years

was a reasonable threshold for scrutiny under our 2010 assessment of MA plan enrollments, this number could fluctuate. As a result we are not proposing to revise our regulations to specify a specific threshold. If, using the principles described above, we identify an alternative threshold for scrutiny, we will include this information in our annual Call Letter. We solicit comment on this approach and whether we have provided sufficient clarity on how we will determine whether a low-enrollment plan will not be renewed.

D. Changes To Improve Payment Rules and Processes

This section addresses four payment issues under Part C. The first proposal outlines a new proposed dispute and appeal rights process for risk adjustment data validation audit findings that result in payment errors. The second proposal would require an actuarial certification for Part C bids. The third proposal under this section would clarify how health care prepayment plans (HCPP) and cost plans authorized under section 1876 of the Act must determine acceptable administrative costs. Finally, the last proposal would update our regulations to eliminate a 2 percent minimum update for all rate calculations, other than end-stage renal disease (ESRD), for reasons we set forth below. These provisions are outlined in Table 4.

TABLE 4—IMPROVING PAYMENT RULES AND PROCESSES

Provision	Part 417/422	Part 417/422	Part 423	Part 423
	Subpart	Section	Subpart	Section
Risk Adjustment Data Validation Appeals	Subpart G	Various sections of Part 422.	N/A	N/A.
Payments to Medicare Advantage Organizations—Actuarial Valuation.	Subpart F	§ 422.254	N/A	N/A.
Determination of Acceptable Administrative Costs by Cost Contract and Health Care Prepayment Plans (HCPPs).	Subpart O	§ 417.564	N/A	N/A.
Calculation of the Minimum Percentage Increase under Part C.	Subpart G	§ 422.306	N/A	N/A.

1. Risk Adjustment Data Validation Appeals (§ 422.310)

a. Background

Subpart G of the MA regulations at part 422 describes how payment is made to MA organizations. These payment principles are based on sections 1853, 1854, and 1858 of the Act. Subpart G also sets forth the requirements for making payments to MA organizations offering local and regional MA plans, including calculation of MA capitation rates.

Section 1853(a)(3) of the Act requires that we risk adjust our payments to MA organizations. Risk adjustment strengthens the Medicare program by ensuring that accurate payments are made to MA organizations based on the health status plus demographic characteristics of their enrolled beneficiaries and ensures that MA organizations are paid appropriately for their plan enrollees (that is, less for healthier enrollees expected to incur lower health care costs and more for less healthy enrollees expected to incur

higher health care costs). Accurate payments to MA organizations also help ensure that providers are paid appropriately for the services they provide to MA beneficiaries. In general, the current risk adjustment methodology relies on enrollee diagnoses, as specified by the International Classification of Disease, currently the Ninth Revision Clinical Modification guidelines (ICD–9–CM) to prospectively adjust capitation payments for a given enrollee based on the health status of the enrollee.

Diagnosis codes determine the risk scores, which in turn determine the risk adjusted reimbursement. As a result, physicians and providers must focus attention on complete and accurate diagnosis reporting according to the official ICD-9-CM coding guidelines (that is, coding diagnoses accurately and to the highest level of specificity).

The current risk adjustment model employed in adjusting MA plan payments is known as the CMS Hierarchical Condition Category (CMS-HCC) model. It functions by categorizing ICD-9-CM codes into disease groups called Hierarchical Condition Categories, or HCCs. Each HCC includes diagnosis codes that are related clinically and have similar cost implications. The CMS-HCC model is recalibrated approximately every 2 years to reflect newer treatment and coding patterns in Medicare FFS. In 2007, a demographic data-only payment method was completely phased-out for MA plans, and 100 percent of payment was risk-adjusted. The statute continues to provide us the authority to add to, modify, or substitute for risk adjustment factors if the changes will improve the determination of actuarial equivalence.

b. Risk Adjustment Data Validation Initiatives

MA enrollee HCCs are assigned based on risk adjustment diagnoses from FFS claims and from risk adjustment data submitted to us by MA organizations via the Risk Adjustment Payment System (RAPS). The CMS-HCCs contribute to an enrollee's risk score, which is used to adjust a base payment rate. Essentially, the higher the risk score for an enrollee, the higher the expected health care cost for the enrollee. The HCC data that MA organizations submit to CMS via the RAPS system is self-reported by the MA organization and does not go through a validation review before being incorporated into a given beneficiary's risk-profile. Since there is an incentive for MA organizations to potentially over-report diagnoses so that they can increase their payment, the Agency audits plan-submitted diagnosis data a few years later to ensure they are supported by medical record documentation.

Verifiable medical record documentation is the key to accurate payment and successful data validation. We annually select MA organizations for risk adjustment data validation (RADV) audits. RADV audits are intended to confirm the presence of risk adjustment conditions (that is, diagnoses that map to HCCs) as reported by MA organizations for their enrollees and confirmed via medical record

documentation. RADV audits occur after the final risk adjustment data submission deadline for the MA contract year. We validate the HCC data submitted by MA organizations by reviewing hospital inpatient, hospital outpatient, and physician/practitioner provider medical records. The focus of this medical record review activity is on diagnoses related to the enrollee's HCC profile. Risk adjustment discrepancies are identified when the enrollee's HCCs used for payment (based upon MA organization-submitted data) differ from the HCCs assigned based on the medical record, pursuant to the RADV audit process. Risk adjustment discrepancies can be aggregated to determine an overall level payment error. In turn, payment error for a sample of contract enrollees can be extrapolated to calculate a contract-level payment error estimate.

From 1999 until 2003, our payment validation activity for the M+C program had both an educational and audit focus and was intended to improve the accuracy of the risk adjustment data that was being submitted to CMS for payment. Payment adjustments were limited to enrollee-level adjustments for those enrollees sampled in the payment validation audit. At the time, only 10 percent of the MA payment amount was risk adjusted. As a result, payment recovery amounts for the small number of plans audited was very small. Since payment year 2004 was the first year for which MA payments were based on the current HCC risk adjustment model, we considered payment years 2004 through 2006 as pilot years for the purpose of RADV and no payment recovery activity occurred. For payment year 2007, we began conducting payment adjustments based on statistical RADV MA contract-level payment error audit findings. The existence of contract-level RADV audits is intended to enable us to make contract-level payment adjustments rather than simply adjusting payments for specific enrollees from an audit sample as we have done previously.

On July 17, 2008, we announced a pilot program to more extensively audit MA organizations for payment year 2007 based on calendar year 2006 payment data. In this notice, we announced its plans to make contract-level payment adjustments using payment error findings from a sample of enrollees from each of the selected contracts. This was a major change to our RADV audit approach in that it signaled for the first time the Agency's intent to recover MA organization contract-level payments. As a consequence, this would result in substantially larger payment error than

the previous enrollee-level audits. In 2009, we expanded its RADV audits to randomly selected MA organizations and MA organizations targeted because of the results of an earlier coding intensity study. Both the random and targeted RADV audits were intended to generate statistically valid contract-level payment error estimates based on 2007 payments.

c. RADV Error-Rate Calculation Disputes and Reconsiderations

Neither the MMA nor existing Medicare Advantage regulations expressly provide for an administrative appeals process that would apply to RADV-related disputes involving MA organizations undergoing RADV audits. Until 2008, because RADV audit payment adjustments were limited to sampled beneficiary-level findings only, the overall impact of these payment adjustments on MA organizations was relatively small. Nevertheless, affected MA organizations requested that we provide some type of appeal remedy for disputing RADV audit results. In response to this request, for the RADV audit activity that occurred for payment year 2005, MA organizations that disputed our RADV audit findings were permitted to do so via an administrative process known as documentation dispute. Under documentation dispute, MA organizations selected for RADV audit could dispute enrollee-level HCC findings based on the application of the ICD-9-CM guidelines. This documentation dispute process allowed MA organizations to submit new medical record documentation and clarifying documentation. Our medical record review contractors reviewed this clarifying documentation via the documentation dispute process and if this documentation overturned the initial discrepancy determination, the contractor would recalculate the MA organization's payment error estimate and make payment adjustments based upon the revised payment error estimate.

d. Proposed Addition of Medicare Advantage Organization Risk Adjustment Data Validation—Dispute and Appeal Procedures

Our experience to date in conducting RADV audits has led us to propose affording MA organizations undergoing RADV audits the formal dispute and appeal rights as possible remedies for RADV audit findings that result in payment errors. Since neither the statute nor existing MA program regulations specify RADV dispute or appeal requirements, we are, under our authority to establish MA program

standards by regulation at section 1856(b)(1) of the Act, proposing additions to part 422, subpart G at new § 422.311, to specify RADV dispute and appeal rights for MA organizations. Specifically, we propose allowing MA organizations that have undergone RADV audit(s) to—(1) submit physician and other practitioner signed attestations for physician and other outpatient medical records with missing or illegible signature and/or credentials that could result in a payment error; (2) dispute certain other types of medical record review-related errors through the use of a documentation dispute process; and (3) appeal our RADV payment error calculation. By availing themselves of these RADV dispute and appeal processes, MA organizations may be able to reduce their RADV payment error and thereby, reduce their overall estimated MA payment error. Therefore, we are proposing the following provisions under part 422:

- At § 422.2, we provide definitions of six terms that pertain to Risk Adjustment Data Validation (RADV) activities and thereby, relate to our proposals for implementing RADV dispute and appeal processes.

- At § 422.311, we propose adding a new section to Subpart G—RADV audit dispute and appeal processes—describing procedures that we would implement to afford MA organizations undergoing RADV audits the opportunity to have certain potential RADV payment errors addressed in advance of RADV-audit-related payment error determinations being made, and other types of confirmed payment errors overturned. At § 422.311(a) and (b), we summarize the procedures that we undertake to conduct RADV audits of MA organizations. Beginning with § 422.311(c), we propose implementing three RADV-related dispute and appeal procedures that MA organizations could undertake to reduce their RADV payment error to include—

- Physician/practitioner attestation(s);
- Documentation dispute; and
- RADV payment error calculation appeal.

Analysis of data originating from medical records submitted by MA organizations that have undergone RADV audit indicates that a substantial percentage of medical record-related payment error determinations are due to missing or illegible signature or credentials on medical records. Medicare program rules dictate the necessity of physician signatures on medical records, and MA risk adjustment requirements dictate that risk adjustment diagnosis data be

accepted from health services that were conducted by certain physician specialties. Therefore, RADV requirements dictate that in addition to the presence of diagnosis information that would support HCCs submitted by MA organizations, physician signatures and credentials must be present on medical records. Medical records with missing or illegible signatures and/or credentials are scored as errors under RADV audit procedures. We estimate that if given the opportunity to do so, many physicians and other practitioners that provided the diagnosis information on RADV-reviewed medical records would in fact attest that they documented the information in these medical records, even though signatures and credentials were missing. The presence of a signature or credential attestation to accompany these medical records would in our opinion, provide justification for preventing both contract-level and national-level RADV payment errors that may otherwise originate from medical record signature and/or credential discrepancies only. They would not, however, be acceptable to address any issues outside the RADV audit process.

Therefore, under our authority to establish MA program standards by regulation at section 1856(b)(1) of the Act and the authority at section 1853(a)(3) of the Act to risk adjust payments for MA organizations, at newly established § 422.311(c)(1), we are proposing to implement a process that would allow MA organizations to voluntarily submit CMS attestations (that is, only attestations developed and pre-populated by CMS). These attestations would be signed by physicians/practitioners who would attest responsibility for conducting and documenting the health services in the physician and outpatient medical record(s) being submitted for RADV audit. We specify at § 422.311(c)(1)(ii) and (iii) that MA organizations would be eligible to use attestations to address signature and/or credential-related discrepancies only from physician or outpatient medical records; attestations would not be allowed to address signature and/or credential-related discrepancies found on inpatient medical records. We do not believe it is necessary to permit attestations for inpatient medical records. The proposed use of an attestation would not in any way supplant the medical record, nor would it permit attesting physicians/practitioners to alter the existing medical record.

Based on our recent RADV experience, the percentage of payment error associated with signature and

credentials for inpatient medical records is relatively small. Furthermore, MA organizations would not be permitted to use attestations as a vehicle for introducing new HCCs for payment consideration.

At § 422.311(c)(1)(C)(iv), we indicate that we would prospectively notify MA organizations that if their one best medical record necessary to validate an audited HCC was missing a physician/practitioner signature or credential, the MA organization would be permitted to submit a CMS RADV attestation along with the medical record, to fulfill the requirement that medical records contain physician/practitioner signatures and credentials.

We describe the process that we would jointly undertake to review attestations submitted for our review at § 422.311(c)(1)(iv) and (v). Only CMS-generated attestations that meet certain requirements described at § 422.311(c)(1) and (d) are eligible for consideration. Failure to meet these requirements would result in us not reviewing submitted attestations. CMS attestations that have been altered or amended (for example, striking out pre-populated words and replacing them with hand-written replacement words) without instruction or written confirmation by CMS will not be accepted. Attestations must accompany the medical record at the same time that the medical record is submitted to CMS for RADV audit. MA organizations may not submit attestations before or after submission of their RADV medical records. Attestations must originate from the physician/practitioner whose medical record accompanies and corresponds to the attestation. We will not accept attestations or medical records from any party other than the MA organization. Organizations may not submit attestations during the documentation dispute or RADV reconsideration processes described at § 422.311(c)(2 and 3). At § 422.311(c)(1)(iv), we describe the process that we would undertake to review attestations and notify appellant MA organizations of the results of these attestation reviews. Our attestation review determinations would be final and binding upon both parties and would otherwise not be eligible for further appeal.

We believe this proposal benefits both MA organizations and the Government. First, MA organizations will be provided an opportunity to prevent substantially high RADV payment errors that would otherwise be associated with signature and/or credential errors. Second, we benefit by being able to report RADV payment errors that

originate primarily from the lack of diagnosis data necessary to justify submitted HCCs rather than missing signatures and/or credentials or the lack of legible signature and/or credentials. We believe that this is an important distinction given the underlying principles of the risk adjustment payment model—a model that pays MA organizations less for healthy enrollees and more for less-healthy enrollees based upon the existence of diagnostic data in enrollee medical records.

We further propose affording MA organizations the option of disputing other non-signature or credential-types of RADV-related medical record diagnosis coding discrepancies via a proposed documentation dispute process that we describe in new paragraph § 422.311(c)(2) et seq. This proposal is based upon our authority to establish MA program standards by regulation at section 1856(b)(1) of the Act and the authority at section 1853(a)(1)(G) of the Act to risk adjust payments for MA organizations. In order to be eligible for documentation dispute, MA organizations must submit their one best medical record to us in accordance with RADV medical record submission deadlines established by CMS during the RADV medical record request process.

At § 422.311(c)(2)(a), we specify the types of RADV-related errors that would be eligible for the documentation dispute process. The documentation dispute process will apply only to the errors that arise out of operational processing of medical records selected for RADV audit and submitted to CMS by established deadlines. In this context, errors that arise from operational processing mean errors that arise from the collection and processing of medical records for RADV audit. For example, if an MA organization submits a two-page medical record that inadvertently becomes separated into “two” medical records upon receipt by the CMS Medical Record Review Contractor—we would permit the MA organization to resubmit the two-page medical record so that the record can be reviewed in its intended two-page format. At § 422.311(c)(2)(ii), we specify the limitations that we would impose upon the documentation dispute process, namely that MA organizations would not be permitted to dispute any medical record coding discrepancies, nor would MA organizations be permitted to submit altogether new medical records in place of previously submitted medical records. Payment errors that resulted from missing medical records will not be eligible for documentation dispute. A missing

medical record means that no medical record documentation was submitted by the formal CMS-established deadline. MA organizations would not be permitted to use the documentation dispute process as a mechanism for establishing new HCCs for payment consideration. In this context, the term “new HCC” means an HCC that was not previously assigned to an enrollee, because no associated risk adjustment diagnosis data was submitted to CMS for payment.

At § 422.311(c)(2)(iii) and (iv), we indicate that we would prospectively notify MA organizations of RADV payment errors that would be eligible for documentation dispute, describe the documentation dispute process that we would undertake, along with the process that we will undertake to notify MA organizations of the results of documentation dispute reviews. As described at § 422.311(c)(2)(v), our documentation dispute review determination would be final and binding upon both parties and would not otherwise be eligible for further administrative appeal.

We believe affording MA organizations the ability to dispute the operational processing of those medical records that are submitted timely offers MA organizations and CMS a balanced approach for disputing a significant portion of RADV errors. It also does so in a manner that benefits both MA organizations and the Government. Allowing MA organizations to dispute CMS’ operational processing errors provides MA organizations an opportunity to overturn certain types of RADV payment errors and thereby reduce their overall RADV payment error. However, the approach we recommend here that limits MA organizations to disputing only certain types of errors ensures that the integrity of the CMS’ RADV audit process remains intact. We believe this is an important consideration in developing an RADV dispute process that balances the desires of the MA industry and the program integrity interests of the Federal Government. To date, some MA organizations that have undergone RADV audit have been dissatisfied with our medical record review processes and have petitioned CMS to allow additional opportunities to validate HCCs selected for audit. Given the rigor of our existing RADV audit procedures generally and multi-faceted medical record review procedures specifically, we believe this is unnecessary. Indeed, we believe that it is important to understand that while the RADV medical record review process is intentionally a rigorous procedure that

is carried out by several independent CMS contractors, we have structured the overall medical record review process so that MA organizations can successfully submit requested medical records necessary to validate diagnoses that were sent to us for determining payments under risk adjustment.

The rigor surrounding the RADV medical record review process is well established and has been known to the MA industry for several years. For purposes of clarity and context, we summarize that process here. To validate the CMS–HCCs selected for audit, MA organizations need only submit medical record documentation for each enrollee CMS–HCC requested by CMS for the specified audit time frame. The medical record must reflect a date of service that occurred during the respective audit period. We instruct each MA organization to select and submit the one best medical record necessary to support each enrollee CMS–HCC being validated. Furthermore, we provide each MA organization undergoing RADV audit 12 weeks to submit the one best medical record for validation. Once requested medical records have been received, for any identified RADV errors, we conduct two rounds of medical record review by two independent contractors. Medical record review contractors employ certified coders to review medical records. The purpose of the second independent medical record review is to confirm discrepancies found in the initial review. To ensure the integrity of the medical record review process and the accuracy of the medical record review findings, the second medical record review contractor is blind to the findings from the first medical record review contractor when it examines medical records that the first medical record review contractor determined were discrepant. Further, all discrepant records with coding discrepancies are reviewed twice. First they are reviewed by a primary coder and then they are forwarded to a senior-level expert coder for review confirmation. As needed, consultation from physicians is also provided. Finally, we undertake robust medical record coder inter-rater reliability (IRR) testing to ensure that medical record review activity is consistent and the application of CMS RADV coding guidelines are applied uniformly and fairly.

Together in its entirety, we believe the RADV medical record review process is thorough and it affords MA organizations ample opportunity to successfully meet RADV audit standards. We believe that affording MA organizations additional opportunities

for attestation and documentation dispute to meet CMS' RADV medical record documentation standards, beyond those specified at proposed § 422.311(c)(1) and (2) et seq., would be an unnecessary use of government resources that is unlikely to result in any meaningful change in RADV audit results.

Pursuant to our authority to establish MA program standards by regulation at section 1856(b)(1) of the Act and the authority at section 1853(a)(1)(G) of the Act to risk adjust payments for MA organizations, we are adding § 422.311(c)(3) to establish an appeals process whereby RADV payment error calculations may be subject to appeal. Unlike our proposed attestation process described at § 422.311(c)(1) and proposed documentation dispute process describe at § 422.311(c)(2) which afford MA organizations the opportunity to dispute aspects of our medical record review process, the RADV payment error calculation appeal process is specifically designed to afford MA organizations the opportunity to appeal our contract-level RADV payment error calculation. Under the proposed RADV payment error calculation appeal process, we are establishing a three-level appeal process whereby MA organizations may—

- Seek reconsideration;
- Appeal the reconsideration decision to an independent CMS hearing officer; and
- Appeal the decision of the independent CMS hearing officer to the CMS Administrator.

Unlike the proposed attestation and documentation dispute processes described in our proposed regulations at § 422.311(c)(1) and (c)(2), our proposed RADV payment error calculation appeal process has several layers of appeal available to MA organizations. Our proposed dispute processes described at § 422.311(c)(1) and (c)(2) afford MA organizations only one level of dispute consideration because the RADV medical record audit process already provides multiple layers of strong and overlapping review and independence. These measures ensure robust layers of internal checks and balances that help maintain the integrity of the medical record review process. Therefore, we do not believe that the attestation or document dispute processes require additional levels of dispute. Given the complexity of RADV audits in general, and the calculation of RADV-related error rates in particular, we do believe it's prudent to afford appellate MA organizations multiple-layers of RADV-related payment error appeal.

At § 422.311(c)(3)(ii) we specify that MA organizations may not under the RADV payment error calculation appeal process appeal medical record review errors nor may MA organizations seek formal appeal of physician or practitioner signature or credential-related review errors. Medical record review-related issues will be resolved as a result of the rigorous medical record review process and the proposed attestation and documentation dispute processes described earlier in this proposed regulation. In accordance with our proposed regulation at § 422.311(c)(3)(i), the RADV payment error calculation appeals process only applies to errors identified in the RADV payment error calculation. MA organizations cannot utilize the payment error calculation appeal process as a method for submitting any medical records for consideration in the calculation of the payment error. In order to be eligible for RADV payment error calculation appeal, MA organizations must adhere to established RADV audit requirements, including the submission of medical records in the manner and by the deadlines specified by CMS.

Furthermore, MA organizations cannot appeal the CMS' payment error calculation methodology. Our justification for excluding methodological appeals is two-fold. First, the methodology that we employ to calculate RADV payment errors is methodologically sound and academically defensible. We intend to ensure that all MA organizations understand the RADV payment error calculation methodology by providing annual notice to all MA organizations of the methodology that will be employed for calculating Part C payment errors. MA organizations that object to CMS' RADV payment error calculation methodology will be given an opportunity to provide comment to us under the Agency's annual notice of RADV audit methodology. Second, in addition to providing an annual notice of RADV audit methodology, we will provide an expanded explanation of methodology as part of each audit report of findings that we send to MA organizations that undergo RADV audit. Included in this expanded explanation of methodology will be RADV payment error calculation factors unique to each audited MA organization that will enable the MA organization to independently calculate its own RADV payment error.

At § 422.311(c)(3)(iii) and (v), we specify that MA organizations will be notified of their RADV payment error calculation appeal rights at the time

CMS issues a RADV audit report to that organization. MA organizations will have 30 days from the date of this notice to submit a written request for reconsideration of its RADV payment error calculation. A request for reconsideration must specify the issues with which the MA organization disagrees, the reasons for the disagreements and explain why the organization believes the issues are eligible for reconsideration. The request for reconsideration may include additional documentary evidence that the MA organization considers material to the reconsideration, though MA organizations are prohibited from submitting medical record-related evidence such as new or previously submitted medical records or physician or practitioner attestations and from appealing any issues pertaining to the methodology applied in any part of the RADV audit. At § 422.311(c)(3)(iv), we further specify that the MA organization bears the burden of proof to demonstrate that CMS' RADV payment error calculation was clearly incorrect.

We describe the proposed conduct of a RADV payment error calculation reconsideration, the decision of the reconsideration official and the effect of the CMS reconsideration decision official at § 422.311(c)(3)(e) and (f).

At § 422.311(c)(3)(v) and (vi), we describe the first level of RADV payment error calculation appeal, the request for reconsideration of our RADV payment error calculation. Under this process a CMS official or our contractor not otherwise involved in error-rate calculation activity reviews our RADV payment error calculation and any written evidence submitted by the MA organization that pertains to CMS' RADV payment error calculation, recalculates the payment error utilizing our RADV payment error calculation methodology as specified in our standard operating procedures, and renders a determination whether the RADV payment error calculation is accurate. This CMS official or CMS contractor (not otherwise involved in RADV error-rate calculation activity) may calculate and arrive at a different RADV payment error. Whether the official or contractor agrees with our payment error calculation or overturns this calculation and establishes a new RADV payment error, this party's RADV payment error calculation determination is issued to a CMS reconsideration official. The CMS reconsideration official reviews their analysis and makes a determination whether to accept or reject the findings of the CMS official or CMS contractor that recalculated the RADV payment error. In instances when

the CMS official or contractor recommends overturning CMS' RADV payment error calculation and the reviewing CMS reconsideration official agrees with the newly calculated RADV payment error, we issue a reconsideration decision which informs the appealing MA organization in writing of its reconsideration decision, in effect, notifying the MA organization of its new RADV payment error. If the reconsideration official upholds the decision of the CMS official or contractor to sustain our initial RADV payment error calculation, the reconsideration official similarly notifies the appellant MA organization of its determination. In either instance, the decision of the reconsideration official is final and binding unless a request for hearing is filed by CMS or the appellant MA organization.

At § 422.311(c)(4), we propose to allow CMS or MA organizations that are dissatisfied with the decision of the CMS reconsideration official described at § 422.311(c)(3) et seq., to request a second level of RADV payment error calculation appeal, a hearing on their RADV payment error calculation determination. CMS or MA organizations choosing to pursue a hearing must file a request for hearing within 30 days of the date the MA organization receives our written RADV payment error calculation reconsideration decision as described at § 422.311(c)(3)(vi). CMS or MA organizations requesting a hearing must do so in writing, include a copy of the CMS reconsideration official's decision to either uphold or overturn our RADV payment error calculation, and specify the findings or issues in that reconsideration decision that they disagree with and why they disagree with them. The hearing will be conducted by the CMS Office of Hearings and presided over by a CMS Hearing Officer who neither receives testimony nor accepts any new evidence that was not presented with the request for reconsideration of the RADV payment error calculation. The hearing will be held on the record, unless the parties request, subject to the hearing officer's discretion, a live or telephonic hearing. The hearing officer may also schedule a live or telephonic hearing upon their own motion. The CMS hearing officer is limited to the review of the record that was before us when we made both our initial RADV payment error calculation and our reconsidered RADV payment error calculation.

The hearing officer has full power to make rules and establish procedures, consistent with the law, regulations, and

CMS rulings. These powers include the authority to take appropriate action in response to failure of an organization to comply with such procedures.

As described at proposed § 422.311(c)(4)(iv), the CMS hearing officer reviews and decides whether the reconsideration official's decision was correct and notifies CMS and the MA organization in writing of his/her decision, explaining the basis for the decision. In effect, the CMS hearing officer's ruling either upholds or overturns the RADV payment error calculation. The Hearing Officer does not recalculate the error and offer either party an alternative RADV payment error. In instances where the hearing officer overturns the RADV payment error calculation, the hearing officer issues their written determination to CMS and the MA organization, in effect, notifying both parties that we must recalculate the organization's RADV payment error. If the Hearing Officer upholds the decision of the CMS reconsideration official regarding the RADV payment error calculation, the Hearing Officer similarly notifies CMS and the MA organization of his/her determination. The Hearing Officer's decision is final and binding, unless the decision is reversed or modified by the CMS Administrator in accordance with § 422.311(c) (5).

The third level of RADV payment error calculation appeal that MA organizations can request is discretionary review by the CMS Administrator. We describe this proposed process at § 422.311(c)(5) *et seq.* At this level of appeal, CMS or the MA organization can appeal the decision of the CMS Hearing Officer by requesting that the CMS Administrator review the CMS Hearing Officer's determination. Parties requesting CMS Administrator review would have to request the review within 30 days of receipt of the CMS Hearing Officer's determination. If the Administrator agrees to review the case, the Administrator reviews the Hearing Officer's decision as well as any other information included in the record of the Hearing Officer's decision and determines whether to uphold, reverse, or modify the CMS Hearing Officer's decision. The Administrator's determination is final and binding.

Based on our experience with appeals of MA and Medicare Part D program contract determinations, we have determined that it is necessary for us to establish a "compliance date" to use as a reference point in issuing a ruling regarding RADV audit findings. By way of this proposed regulation at § 422.311(b)(2), we are requiring that the

compliance date for meeting Federal regulations requiring MA organizations to submit medical records for the validation of risk adjustment data, (§ 422.310(e)) also be the due date when MA organizations (or their contractor(s)) selected for RADV audit, must submit medical records to CMS. We will inform an MA organization in writing regarding selection for RADV audit including the due date for submission of medical records. Without a specific date as a reference point for evaluating compliance, MA organizations could choose to assert that while they were unable to meet RADV audit requirements on the date we specified as the due date for medical record submission, they were later able to do so. Under this scenario, organizations would be free to assert the right to submit medical records in place of, or in addition to, records that were, or were not, as the case may be, submitted to us by the RADV audit due date. Accordingly, if we proceeded to conduct our RADV audit, issue a report of findings, and attempt to collect any identified overpayments, affected MA organizations could counter that while they did not have medical records to justify a particular HCC-level payment at the time due, they now have such records. Therefore, we should re-open the audit, review the new medical records and adjust our report of findings accordingly. The medical record review process could continue ad-infinity, preventing us from closing out RADV audits and collecting any identified overpayments.

We welcome comments on all aspects of these proposed rules.

2. Payments to Medicare Advantage Organizations—Actuarial Valuation (§ 422.254)

We propose to amend the regulation to expressly require an actuarial certification for Part C bids. Operationally, we require an actuarial certification to accompany every bid, for both Parts C and D. A qualified Oactuary who is a Member of the American Academy of Actuaries (MAAA) must complete the certification. The objective of obtaining an actuarial certification is to place greater responsibility on the actuary's professional judgment and to hold him/her accountable for the reasonableness of the assumptions and projections. This requirement is already set forth in the part D regulations at § 423.265(c)(3). This proposed change in the part C regulation text will bring the part C regulation at § 422.254(b)(5) in line with current requirements and Part D.

3. Determination of Acceptable Administrative Costs by Cost Contracts and Health Care Prepayment Plans (§ 417.564)

Our requirements for the apportionment and allocation of administrative and general costs for health care prepayment plans (HCPPs) authorized under section 1833(a)(1)(A) of the Act and cost contractors authorized under section 1876 of the Act are set forth at § 417.564. As provided under § 417.802(a), with limited exceptions, allowable costs for HCPP reimbursement are the same as those for reasonable cost HMOs and CMPs as specified in Subpart O of Part 417. Both section 1833(a)(1)(A) of the Act (for HCPPs) and section 1876(h)(2) of the Act (for cost HMOs and CMPs) incorporate the definition of “reasonable cost” in section 1861(v) of the Act, which used to govern reimbursement to providers of services under Part A prior to the enactment of Prospective Payment Systems (PPS). Because that definition was originally established with respect to Original Medicare providers, we believe that it is appropriate to interpret and apply the principles in section 1861(v) in the managed care context. We accordingly propose to revise the regulations governing payments to HCPPs and cost HMOs/CMPs to clarify how we believe the reasonable cost principles in section 1861(v) should apply to HCPPs and HMOs/CMPs by specifying the methodologies that must be used in determining the different allowable administrative costs for both such entities.

We have noted in recent audits of HCPP and section 1876 cost contractors uncertainty regarding what constitutes a “reasonable” level of administrative costs incurred by these entities. In conducting audits, we have not always been able to confirm that HCPP and cost contractors authorized under section 1876 of the Act were calculating their administrative costs in a manner that has allowed us to verify that they have followed appropriate practices.

In order to remove any uncertainty on the part of HCPP and cost contractors authorized under section 1876 of the Act, we propose revising § 417.564(b)(2) to clarify how HCPP and cost contractors authorized under section 1876 of the Act must determine “reasonable” administrative costs. As proposed at § 417.564(b)(2)(iii), personnel costs claimed in administering both HCPP and cost

contracts authorized under section 1876 of the Act must be linked to the specific administrative function performed by persons, at a specific rate of pay, for a specified period of time. We also propose to clarify that this level of information must be available to CMS upon request or in the course of a review. Additionally, we propose revising § 417.564 by adding a new paragraph (c) that specifies that, in order for costs to be considered “reasonable costs” within the meaning of section 1861(v) of the Act, which expressly excludes “incurred cost found to be unnecessary in the efficient delivery of needed health services,” the following costs must be excluded when computing reimbursable administrative costs:

- Donations.
- Fines and penalties.
- Political and lobbying activities.
- Charity and courtesy allowances.
- Spousal education.
- Entertainment.
- Return on equity.

Because we are simply clarifying our reporting and recordkeeping requirements, by clarifying what costs an HCPP may report in its cost report as administrative costs for reimbursement by the government, we do not believe this provision would increase burden or costs for plan sponsors. However, we solicit comment on our assumptions.

4. Calculation of the Minimum Percentage Increase Under Part C (§ 422.306)

Section 5301 of the DRA added section 1853(k) of the Act to create a single rate book for calculating MA payments and applicable adjustments. The DRA also modified the methodology for updating the MA payment rates by adding section 1853(k)(1)(B) of the Act. Beginning in 2007, the statute requires for purposes of calculating the minimum percentage increase rate that the previous year’s benchmarks be updated annually using only the national per capita MA growth percentage as described in section 1853(c)(6) of the Act. Prior to 2007 the minimum percentage increase rate was the greater of 102 percent of the MA capitation rate for the preceding year or the MA capitation rate for the preceding year increased by the national per capita MA growth percentage for the year.

Since the statute, as revised by the DRA, no longer provides for the 2 percent minimum update, we can no longer apply it to the MA rates. The 2 percent minimum update still applies to

the end stage renal disease MA update because the statute at section 1853(a)(1)(H) of the Act provides that ESRD rates are to be calculated in a manner consistent with the way those rates were calculated “under the provisions of [section 1853 of the Act] as in effect before the date of enactment of the MMA.” The pre-2003 version of section 1853 of the Act included the 2 percent minimum update. Therefore, we propose to revise § 422.306 to eliminate the 2 percent minimum update for all rate calculations other than ESRD.

E. Changes To Improve Data Collection for Oversight and Quality Assessment

This section of the rule outlines four proposals related to improving Part C and D data collection for oversight and quality assessment. The first proposal addresses quality improvement projects and data on quality and outcomes measures under Part C. As part of this proposal, we would use data collected by Quality Improvement Organizations for MA quality improvement and performance assessment purposes.

The second proposal addresses payment for beneficiary surveys. We would require, consistent with other surveys under the MA program that MA and Part D sponsoring organizations pay for the data collection costs of the Consumer Assessment of Healthcare Providers and Systems (CAHPS) annual survey beginning in 2011.

Under our third proposal, we propose to require that each Part C and Part D sponsor be subject to an independent yearly audit of Part C and Part D measures (collected pursuant to our reporting requirements) to determine their reliability, validity, completeness, and comparability in accordance with specifications developed by us.

Finally, the last proposal would amend our rules on the collection and use of prescription drug event data for nonpayment-related purposes. Previously our rules addressed only the collection of the original 37 data elements for non-payment related purposes. In this rule, we are proposing to collect all data elements included on the drug event record for non-payment purposes. We also propose to provide for the limited release of plan identifiers to certain government grantees.

For the reasons set forth below, we believe each of these proposals is necessary to ensure continued quality improvement in the Part C and D programs.

TABLE 5—IMPROVE DATA COLLECTION FOR OVERSIGHT AND QUALITY ASSESSMENT

Provision	Part 422		Part 423		Part 480
	Subpart	Section	Subpart	Section	
Requirements for Quality Improvement Programs under Part C.	Subpart D	§ 422.152,	N/A	N/A	§ 480.140.
Require that Sponsors pay for the Consumer Assessment Health Plan Survey (CAHPS).	Subpart D	§ 422.153	Subpart D	§ 423.156	N/A.
Require validation of reporting requirements ..	Subpart D	§ 422.152(b)(5)	Subpart D	§ 423.514	N/A.
Allow collection of all PDE data elements to be collected for non-payment purposes.	N/A	§ 422.516, § 423.514 ..	Subpart D	§ 423.505	N/A.

1. Requirements for Quality Improvement Programs Under Part C (§ 422.152, § 422.153, and § 480.140)

Section 1851(d)(4)(D) of the Act requires us to make available to MA eligible individuals' information comparing MA plan options, including information on plan quality and performance indicators to the extent this information is available. Separately, section 1852(e)(1) of the Act requires that each MA organization have an ongoing quality improvement program for the purpose of improving the quality of care provided to enrollees in each MA plan offered by the MA organization. Section 1852(e)(3)(A) of the Act requires that, as part of this quality improvement program, MA organizations collect, analyze, and report data that permits the measurement of health outcomes and other indices of quality as part of their quality improvement program for their coordinated care plans. To the extent that local PPO, regional PPO, PFFS, and MSA plans have a network of contracted providers, these plan types must meet the same quality improvement requirements as other coordinated care plans.

Section 1852(e)(3)(B)(i) of the Act generally limits the collection of data on quality, outcomes, and beneficiary satisfaction under section 1852(e)(3)(A) to facilitate consumer choice and program administration to "the types of data" that were collected as of November 1, 2003, however, section 1852(e)(3)(B)(ii), titled "Changes in Types of Data," provides for the Secretary to "change the types of data that are required to be submitted under subparagraph (A) after submitting to Congress a report on the reasons for such changes that was prepared in consultation with MA organizations and private accrediting bodies." Section 1852(e)(3)(B)(iii) also makes clear that the limitation in section 1852(e)(3)(B)(i) shall not be construed as "restricting the ability of the Secretary to carry out the duties under section 1851(d)(4)(D)" to

provide beneficiaries with "available" quality information on MA plans.

a. Quality Improvement Programs

The requirement for MA organizations to have ongoing quality improvement programs is codified at § 422.152(a). Under § 422.152(a)(1), MA plans are required to include a chronic care improvement program (CCIP) as part of their quality improvement program that meets the requirements set forth in § 422.152(c). As specified under § 422.152(a)(2), MA organizations are also required to include quality improvement projects as part of their quality improvement program that are expected to have a favorable effect on enrollee health outcomes and enrollee satisfaction, and meet requirements established in § 422.152(d). Under our current regulations at § 422.152(c) and § 422.152(d), MA organizations have flexibility to develop criteria for CCIPs and initiate any quality improvement project that focuses on clinical and non-clinical areas based on the needs of their enrolled population.

Based on our continued experience with the MA program and due to inconsistent methods used across organizations, we are concerned that relying on MA organizations to establish their own CCIPs and quality improvement projects may not lend itself to effectively compare plans by beneficiaries and to manage and report projects. More importantly, we have concerns that these projects are not addressing quality improvement areas that we believe reflect beneficiary needs. For example, some projects may be designed to improve processes only without linking the processes to clinical outcomes. For example, improving the timeliness and effectiveness of referrals to specialists, as measured by process measures, may have little or no impact on improved health outcomes for beneficiaries. We are interested in MA organizations focusing on individual as well as population specific health risk needs (for example, MA organizations' use of data sources internal to their

organizations to identify clinical outcomes that not only fail to meet national averages, but also jeopardize the overall health and quality of life of the beneficiary).

As a result of our concerns, we are proposing to revise § 422.152(a)(1) and § 422.152(a)(2) to require that MA organizations conduct CCIPs in patient populations and quality improvement projects in areas identified by CMS based on our review of data collected from MA organizations and the population served by the plans. We propose to determine what areas would most benefit from quality improvement and will provide guidance on specific quality improvement projects for MA organizations to implement, either based on that organization's specific quality improvement needs, or quality improvement needs for MA plans generally. We also will suggest methods and processes by which to manage a quality improvement project as appropriate.

Using the HPMS, Medicare Managed Care Manual, and other means of communication that CMS determines to be appropriate, we will annually inform MA organizations individually and/or generally which patient populations and areas we have determined would benefit most from a CCIP and quality improvement project, respectively.

b. New Quality Measures

As we strengthen our oversight of quality improvement programs implemented by MA organizations, we believe that there is also a need for us to collect additional data on quality and outcomes measures in order to better track plan performance. We currently collect from MA organizations data on quality, outcomes, and beneficiary satisfaction under Healthcare Effectiveness Data and Information Set (HEDIS®), Health Outcome Survey (HOS), and Consumer Assessment Health Providers Survey (CAHPS®). We anticipate additional collection and reporting of the same types of data on health outcomes and quality measures

that we currently collect as part of these processes.

We believe that the collection of these data is consistent with our authority under section 1852(e)(3)(A) of the Act, and do not believe that the limitation described under section 1852(e)(3)(B) of the Act limits this proposed additional data collection because the data collected would be of the same “type” of data that we currently collect as part of the HEDIS®, HOS, and CAHPS® processes. Examples of additional areas on which we plan to collect data are post-surgical infections or patient falls. Therefore, we are proposing to modify § 422.152(b)(3) and § 422.152(e)(2) to require MA plans to collect, analyze, and report quality performance data identified by CMS that are of the same type of data that plans are currently required to collect and report to CMS. Consistent with the Paperwork Reduction Act, we will provide the public at least two opportunities for public comment before imposing additional quality-related collection and reporting requirements.

c. Use of Quality Improvement Organization Review Information

The mission of the Quality Improvement Organization Program, as authorized under section 1862(g) and Part B of title XI of the Act, is to improve the effectiveness, efficiency, economy, and quality of services delivered to Medicare beneficiaries. We contract with one organization in each state, as well as the District of Columbia, Puerto Rico, and the U.S. Virgin Islands, to serve as that state/jurisdiction’s Quality Improvement Organization (QIO) contractor. QIOs are private, mostly not-for-profit organizations, which are staffed by professionals, mostly doctors and other health care professionals, who are trained to review medical care and help beneficiaries with complaints about the quality of care and to implement improvements in the quality of care available throughout the spectrum of care. Over time, QIOs have been instrumental in advancing national efforts to motivate providers in improving the quality of Medicare services, and in measuring and improving outcomes of quality.

Data collected by QIOs to accomplish their mission represent an important tool for CMS in our efforts to improve quality under the MA program. QIOs collect survey, administrative, and medical records data in order to monitor and assess provider performance. These data are frequently required by scope of work contracts administered by CMS to assess whether or not QIOs are meeting performance goals.

Certain QIO data could be used to develop a standardized core set of clinical and non-clinical quality and performance measures that could be applied to all MA plans in order to allow beneficiaries to make better comparisons across all MA plan types and make an informed decision when selecting a plan. These measures could be used to rate plans according to their performance. To support efforts to provide meaningful information to beneficiaries when selecting an MA plan, we also plan to develop minimum performance levels and requirements that address clinical and non-clinical areas. In addition to tracking plan performance, these data could also be used to ensure plan compliance with MA contract requirements and support compliance or enforcement actions against plans that are poor performers on certain quality and performance measures. These data would also allow us to create a competitive value-based purchasing program based on quality of care.

Therefore, we plan to use one particular type of information already collected by QIOs and retool the data elements to make them specific to beneficiaries enrolled in MA plans. This information is quality review study (QRS) information, which is defined in 42 CFR 480.101(b). A QRS is “an assessment, conducted by or for a QIO, of a patient care problem for the purpose of improving patient care through peer analysis, intervention, resolution of the problem and follow-up.” QRS information means all documentation related to the QRS process. We intend to collect from the QIO only the data that relates to MA plan beneficiaries, providers, practitioners, and services. We could then aggregate the data to the applicable MA plan based on beneficiary enrollment. Accordingly, we are proposing to add a new § 422.153 to indicate that we will collect from the QIOs and use quality review study information that is generated, collected, or acquired by QIOs under part 42 CFR 480. We intend to use these data for the following functions: Enabling beneficiaries to compare health coverage options and select among them, measuring performance under the plan, ensuring compliance with plan requirements under Part 422, and other purposes related specifically to MA plans, as specified by CMS. We will not disclose any beneficiary identifiable information. In addition, we are proposing to amend § 480.140 to add a new paragraph (g), authorizing CMS’s use of quality review study information

solely for the purposes specified in § 422.153.

2. CAHPS Survey Administration Under Parts C and D (§ 417.472, § 422.152, and § 423.156)

In accordance with the 1997 Balanced Budget Act mandate to collect quality assessment data about health plans, we began collecting data in 1998 for the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey of enrollees in Medicare Advantage (MA) plans (then called Medicare+Choice plans). In addition, cost contractors under section 1876 of the Act have also been participating in the CAHPS survey process with respect to their enrollees. We have continued to conduct this annual CAHPS survey at no cost to MA organizations or section 1876 cost contractors. After passage of the Medicare Modernization Act (MMA), we began administering a Part D version of this survey in 2007 to Prescription Drug Plans (PDPs) and Medicare Advantage-Prescription Drug Plans (MA-PDs) in accordance with § 423.156 and § 422.152.

Under sections 1857(e) (1) and 1860D–12 of the Act, the Secretary may add additional terms to the contracts with MA organizations and Part D sponsors as deemed necessary and appropriate. Similarly, in the case of cost contracts under section 1876, such new contract terms may be added under section 1876(i)(3)(D). As explained below, we are proposing on the basis of this authority, that MA, Part D, and section 1876 cost contracts will be amended to require MA organizations, Part D sponsors, and cost contractors to pay for the data collection costs of the annual CAHPS survey beginning in 2011.

In the 2010 Call Letter to Part C and D sponsoring organizations, we indicated that all MA and Part D contracts with at least 600 enrollees as of July 1 of the prior calendar year would be required to pay for the data collection costs of the CAHPS survey starting with the administration of the 2011 annual CAHPS survey. This proposal is intended to codify this requirement in the Part C and Part D regulations at § 423.156 and § 422.152, and for cost contractors in § 417.472.

The proposal to require MA organizations, Part D sponsors, and section 1876 cost contractors to pay for the data collection costs of the CAHPS survey would apply only to contracts with 600 or more enrollees. For reasons of statistical precision, a target minimum of 300 or more completed Medicare CAHPS Surveys must be received for each contract. In order to

obtain 300 or more completed surveys, we believe plans must have 600 or more enrollees because some enrollees will not be eligible to receive the survey, such as institutionalized enrollees, and not all enrollees selected to be surveyed will respond to the survey.

It is important to note that we conduct other Medicare quality surveys, such as the Hospital CAHPS and the Medicare Health Outcomes Survey (HOS) for which the MAOs are responsible for the cost of the data collection. This model for data collection is standard industry practice. For example, FEHB plans pay for the administration of the CAHPS survey to their members. The data collection model that we are proposing for CAHPS survey process would use the same model that MAOs currently follow for HOS. The National Committee for Quality Assurance (NCQA) certifies vendors to conduct the HOS survey on behalf of CMS. In 2009, MAOs chose from a list of six approved vendors for HOS. We have been moving toward this model for all of our data collection efforts for beneficiary satisfaction surveys. We propose to use a similar model for the Medicare CAHPS survey where Part C & D contractors and section 1876 cost contractors would select a vendor from a CMS list of approved vendors to conduct the survey on their behalf.

While this proposal would shift the cost of data collection to the eligible Part C and D contractors for the Medicare CAHPS survey (section 1876 cost contractors would be able to claim these costs on their cost reports), with this change the sponsoring organizations will have the flexibility of adding their own questions to the Medicare CAHPS survey. The flexibility to add questions will allow them to get feedback about any contract specific issues.

Under this proposal, the following types of contracts would be amended to include a requirement to administer the CAHPS survey—

- All Coordinated Care contracts, including local and regional preferred provider organizations (PPOs) and contracts with exclusively Special Needs Plans (SNPs) benefit packages;
- Cost contracts under section 1876 of the Act;
- Private-Fee-For Service (PFFS) and Medical Savings Accounts (MSA) contracts; and
- Prescription Drug Plans contracts (PDPs).

All plans under Programs of All Inclusive Care for the Elderly (PACE), HCPP—1833 cost plans, and employer/union only (PDP and PFFS) contracts

are excluded from this CAHPS administration.

Under this proposal, the first survey using the new model of data collection would be conducted in early 2011. Contracts that were in effect on or before January 1, 2010, would use the number of enrollees in a plan as of July 1, 2010 to determine whether they are required to conduct the 2011 CAHPS survey. In late 2010, all MA and Part D contracts that are subject to the CAHPS survey requirement in 2011 would need to select an approved Medicare CAHPS survey vendor to administer the survey.

We note that, in addition to approving a list of survey vendors to conduct the survey on behalf of all MA and Part D contracts, we would select the sample of enrollees to be surveyed for each contract, approve survey vendors, provide oversight of survey vendor activities, analyze the CAHPS data for plan ratings, and produce individual-level reports for quality improvement use by MA and Part D contracts. Vendors will be trained by us to collect and submit data within specified timeframes. If we decide to implement this proposal, we will provide further information regarding access to the listing of approved vendors for the CAHPS survey.

3. Validation of Part C and Part D Reporting Requirements (§ 422.516 and § 423.514)

Under sections 1857(e) and 1860D–12 of the Act, we have the authority to establish information collection requirements with respect to MA organizations and Part D sponsors. Under section 1857(e)(1) of the Act, MA organizations are required to provide the Secretary with such information as the Secretary may find necessary and appropriate. Section 1857(e)(1) of the Act applies to PDPs as indicated in section 1860D–12. Pursuant to our statutory authority, we codified these information collection requirements in regulation at § 422.516 and § 423.514, respectively.

Consistent with our regulatory authority to collect information, we developed specific MA and Part D reporting requirements to assist in monitoring the Part C and D programs and to respond to questions from Congress, oversight agencies, and the public. These inquiries include questions about costs, availability of services, beneficiary use of available services, patient safety, grievance rates, and other factors pertaining to MAOs and PDPs. We began collecting Part D information at the inception of the program. Data collected under the Part D reporting requirements currently

include seventeen measures ranging from access to extended day supplies at retail pharmacies to drug benefit analyses. Over time, we have modified the data elements collected as we gained more experience with the program. The current Part D reporting requirements (OMB 0938–0992) may be accessed at http://www.cms.hhs.gov/PrescriptionDrugCovContra/08_RxContracting_ReportingOversight.asp.

We also require routine reporting of specific data elements by MA organizations. Beginning in January 2009, MA organizations are required to report information across 13 measures ranging from benefit utilization to agent training and testing. Similar to the Part D reporting requirements, these measures are designed to enable us to monitor plan performance and to respond to inquiries. The current Part C reporting requirements (OMB 0938–1054) may be accessed at http://www.cms.hhs.gov/HealthPlansGenInfo/16_ReportingRequirements.asp.

In order for us to use the data provided by MA organizations and PDP sponsors, the data must be accurate, valid, reliable, and comparable across plans. Because we have received data of questionable validity from some Part D sponsors, we stated in the 2010 Call letter (<http://www.cms.hhs.gov/prescriptiondrugcovcontra>) that the agency “has received many inquiries from Congress, oversight agencies, and the public about costs, availability of services, beneficiary use of available services, patient safety, grievance rates, and other factors pertaining to MAOs and PDPs. However, to date, we have not been able to address many of these inquiries due to either an absence of data with respect to MAOs or, despite collecting over three years’ worth of data, data of questionable validity submitted by Part D sponsors.” Accordingly, to meet the goals of data validity reliability, and comparability, we indicated in the Call Letter that, “to better enable CMS to respond to inquiries and manage our programs, sponsoring organizations should undertake a data validation audit on reported Part C and Part D data effective for CY2010.” Given the importance of the new Part C and Part D data reporting requirements, we are proposing to require MAOs and Part D sponsors to undertake an independent data validation audit in accordance with CMS specifications on reported Part C and Part D data that would be effective for CY2011. We believe that only an independent data validation audit conducted by an external entity under contract to the MAO or PDP sponsoring organization would ensure that the

results of the audit are in accordance with CMS specifications, that data used to develop plan performance measures are credible to other stakeholders, and that information used to respond to Congressional and public inquiries are reliable. We therefore propose to amend § 422.516 and § 423.514 to state that each Part C and Part D sponsor be subject to an independent yearly audit of Part C and Part D measures (collected pursuant to our reporting requirements) to determine their reliability, validity, completeness, and comparability in accordance with specifications developed by CMS.

We note that we are working with a contractor to develop data validation specifications to ensure that the goals of reliability, validity, completeness, and comparability are met at the conclusion of the data validation audit. These specifications will focus on how organizations and sponsors compile numerators and denominators, take into account appropriate data exclusions, and verify calculations, computer code, and algorithms. In addition, they will be used to inform how the MAOs, cost plans, and Part D sponsors collect, store, and report data. We expect that these specifications will be utilized by the auditors hired by MAOs and Part D sponsors to conduct the data validation audits, the results of which will be forwarded to us. We expect to make these specifications available on our website for public comment early next year. We solicit comment on this approach.

4. Collection of Additional Part D Claims' Elements for Nonpayment-Related Purposes (§ 423.505)

Section 1860D–12(b)(3)(D) of the Act, which incorporates section 1857(e) of the Act provides the Secretary with authority to include in Part D sponsor contracts any terms or conditions the Secretary deems necessary and appropriate, including requiring the organization to provide the Secretary with such information as the Secretary may find necessary and appropriate. Under this authority, on May 28, 2008 we published a final rule that allowed the Secretary to collect Part D “claims” data from the prescription drug event (PDE) record and use the information gathered for non-payment purposes (73 FR 30664). However, this rule limited what data (hereinafter referred to as PDE elements) we may collect and use for non-payment purposes. The rule also described circumstances under which we may disclose the data to other government and external entities, and the limitations associated with any such release.

In 2006 and 2007 there were 37 PDE elements. In 2008 the number of PDE elements collected was expanded from the original 37 elements to 39 elements. The additional PDE elements are “Estimated Rebate Amount Applied to the Point-of-Sale Price” and “Vaccine Administration Fee.” The “Estimated Rebate Amount applied to the Point-of-Sale Price” is the estimated amount of a rebate that the plan sponsor has elected to apply to the negotiated price as a reduction in the drug price made available to the beneficiary at the point of sale. The “Vaccine Administration Fee” is the amount that is charged for the administration of a vaccine separate from the actual vaccine.

In the 2010 Call Letter to sponsoring organizations we noted that we were planning to add a new (40th) element to the PDE record, referred to as the “Prescription Origin Code.” (at <http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/CallLetter.pdf>). The prescription origin code is designed to capture the frequency with which providers use e-prescribing.

The original Part D claims data proposed rule published on October 18, 2006 (71 FR 61447) did not address the collection, for purposes other than payment, of any additional elements that might be added to the original 37 elements. Rather, in the proposed rule, we only included a discussion of the 37 elements that then comprised the PDE record and proposed that we would collect these 37 PDE elements under section 1860D–12(b)(3)(D) of the Act. As a result, as noted in the May 28, 2008 final rule (73 FR 30667) on Part D claims data, interested parties were not afforded an opportunity to comment on whether new elements that were added to the PDE record for 2008 (or any PDE elements that might be added in the future) should be collected under section 1860D–12(b)(3)(D) of the Act, and, consequently, used or disclosed to other parties for non-payment related purposes.

In this rule, we are now proposing to collect all additional PDE elements beyond the original 37 elements under the same authority described in the May 28, 2008 final rule on Part D claims data (that is, section 1860D–12(b)(3)(D) of the Act). As a result, we would be able to use these data for non-payment related purposes. Similarly, under this proposal, we would be able to release these elements to governmental and external entities, under the authority of section 1106 of the Act, using the same process that we now use to release the original 37 elements as described in the May 28, 2008 final rule, and as updated

by the September 18, 2008 interim final rule that incorporated changes made as a result of section 181 of MIPPA. Thus, in this rule, we propose that the release of any additional PDE data elements collected using our authority under section 1860D–12(b)(3)(D) of the Act would continue to be subject to our minimum necessary data policy, our data sharing procedures, and the encryption of certain identifiers and aggregation of cost data to protect beneficiary confidentiality and commercially sensitive data of Part D sponsors.

This proposal would allow us to collect and use for non-payment-related purposes any data obtained as a result of the addition of new elements to the PDE record without undertaking rulemaking for each additional element added in the future. We believe that the May 28, 2008 of Part D Claims Data final rule (73 FR 30664) resolved any statutory ambiguity surrounding our broad authority to collect PDE data under section 1860D–12(b)(3)(D) of the Act. Accordingly, we may use this same authority to collect additional elements that have been added to the PDE since 2007. Once data have been collected under section 1860D–12(b)(3)(D) of the Act, we may use these data for non-payment related purposes and may release PDE data consistent with our minimum necessary policy and our data procedures.

Elements such as rebates applied at the point-of-sale, vaccine administration, and prescription origin code represent claim-level information that once accessed and analyzed, could provide useful insight into operations of the Part D prescription drug benefit program. For example the prescription origin code could be studied to identify how often electronic prescribing is used in practice, and serve as background for policy proposals to further support this practice in the industry. Accordingly, we believe it is appropriate that these elements should be collected under section 1860D–12(b)(3)(D) of the Act.

For the same reason, we believe it would be appropriate to use our authority under section 1860D–12(b)(3)(D) of the Act to collect for non-payment purposes all elements that may be added to the PDE record in the future. We believe that the ability to analyze new claims-related elements added to the PDE record would increase both specific and general knowledge of Medicare beneficiaries' healthcare and the operation of the Part D program and would aid our ability to conduct program oversight, support operational tasks, and provide more information for use in internal and external healthcare

research studies. Moreover, we would not be required to undertake a separate rulemaking and public comment process each time new elements are added to the PDE record, but rather would automatically begin collecting for non-payment purposes elements added to the PDE record using our authority under section 1860D–12(b)(3)(D) of the Act and § 423.505(f)(3) of the regulations. As a result, we would have the ability to analyze these data for nonpayment related purposes in order to identify operational problems or to support future policy proposals without delay. Moreover, because we do not propose to modify our data sharing processes or our minimum necessary data policy with this proposal, any release of these new elements would be subject to the same protections that currently apply to all other Part D PDE data. Thus, we will continue to—

- Ensure that beneficiary, prescriber, or pharmacy identifiers are not released unless absolutely necessary for a project (for example, to link to another database);

- Encrypt Part D plan identifiers and aggregate cost data elements (ingredient cost, dispensing fee, and sales tax) when sharing PDE data with external requesters; and

- Subject each request to our data sharing procedures which includes ensuring that requestors have the appropriate experience and are working for, or on behalf of, a reputable institution and that, when appropriate, make their project results public. External requests concerning beneficiary identifiable data would continue to be reviewed by the CMS Privacy Board, and would require the requestor to sign a data use agreement.

Accordingly, for the aforementioned reasons, we are proposing to amend § 423.505(f)(3) to include all data elements included in all drug claims for purposes deemed necessary and appropriate by the Secretary and consistent with the Paperwork Reduction Act.

In the May 28, 2008 final rule we deemed it necessary to protect various Part D elements when responding to external research requests (as discussed above). Accordingly, beneficiary ID, plan ID, prescriber ID, and pharmacy ID are encrypted prior to release to external entities. However, in the case of beneficiary ID, prescriber ID, and pharmacy ID, this information may be provided in an unencrypted format when needed to link to another data set.

In contrast, under the current rule, there is no exception to the requirement that plan identifiers be encrypted for all external research requests. Under the current regulation, grantees of HHS agencies are treated as external entities and may not access plan identifiers. In contrast, contractors acting on behalf of HHS are not considered to be external entities and may receive unencrypted plan identifiers when necessary for a particular project, due to the provision in § 423.505(m)(iii)(A) that “all elements on the claim are available to HHS.”

Subsequent to publication of the Part D data rule, we have been made aware by some HHS agencies that a number of their grantees are having difficulty conducting some studies without a Plan ID (for example, studies which examine the extent to which plan choice is influenced by a plan’s name could only be determined using actual plan identifiers). These concerns have arisen at time when healthcare costs and patient outcomes under existing healthcare delivery systems are under great scrutiny, necessitating more research on cost-effective alternatives for healthcare delivery.

We are proposing to revise § 423.505(m)(iii)(C) to permit CMS disclosure to HHS grantees of unencrypted plan identifiers when certain conditions are met. We believe these conditions will mitigate the risk of any unauthorized use or disclosure of commercially sensitive plan information. The conditions we propose be met include—

- The plan identifier is essential to the study and there is no other source of CMS data that would substitute for plan identifiers in order to carry out the study;

- The study is key to the mission of the sponsoring agency;

- The study provides significant benefit to the Medicare program; and

- The requestor attests that any public findings or publications will not identify plans or plan sponsors.

In evaluating requestors’ proposals to determine whether these conditions are met, we propose the following evaluation standards:

- Plan identifier, to evaluate the requestor’s rationale to determine whether an encrypted plan identifier would be sufficient for the study design or if the real identifier is necessary for the study.

- Agency mission, we propose to review the requestor’s agency’s rationale for the study and how the study would help the agency achieve its mission.

- Medicare program benefit, we propose to review the requestor’s rationale for the importance of study findings to the Medicare program.

- Public reporting, we propose to require an attestation from the requestor that the requestor will not identify specific plans or plan sponsors in any public reporting.

We are proposing to provide access to unencrypted plan identifiers to HHS grantees for several reasons. First, some HHS agencies accomplish their mission through grants, rather than contracts, and hence cannot rely on the access that is provided to HHS contractors, which means that HHS agencies have differential access to prescription drug event data. In addition, we believe that research performed by HHS grantees will advance the interests of Medicare beneficiaries, who may also be served by other HHS programs. A number of HHS agencies, such as the National Institutes of Health (NIH) and the Agency for Health Care Research and Quality (AHRQ), provide grants for research on topics such as the utilization, adherence, safety, and effectiveness of medications in the elderly and disabled populations which are of key interest to the Medicare program. We anticipate that such studies will assist health care providers in improving medication use in Medicare beneficiaries over time.

Although our proposal is limited to HHS grantees, we also request comments on whether it would be appropriate to extend this proposal to permit grantees of other Federal agencies to have access to plan identifiers when this access may be necessary for a particular research project and that project otherwise meets the conditions described above.

F. Changes To Implement New Policy

This section addresses two policy proposals. In the area of Part D formulary policy, we propose new regulatory requirements affecting the inclusion of protected drug categories and classes on Part D formularies, following the enactment of MIPPA, which made a number of changes to the Part C and D programs. Under Part C, we propose to revise our rules to allow beneficiaries who elect MSAs as a type of health insurance plan to pay only a pro-rated deductible if their MSA deposit is pro-rated because they enroll after January 1. These revisions are detailed in Table 6.

TABLE 6—REVISIONS TO IMPLEMENT NEW POLICY

Provision	Part 422		Part 423	
	Subpart	Section	Subpart	Section
Clarify the MIPPA 176 “Protected Classes” formulary provision.	N/A	N/A	Subpart C ..	§ 423.120(b)(2)(v).
Pro-rating the Plan Deductible for Part C MSA Enrollments Occurring During an Initial Coverage Election Period.	Subpart C ..	§ 422.103	N/A	N/A.

1. Protected Classes of Concern Under Part D (§ 423.120(b)(2)(v))

As noted previously, the MIPPA was enacted on July 15, 2008. Prior to the passage of MIPPA and before the start of the program, we directed Part D sponsors to include on their formularies all or substantially all drugs in six drug categories (that is, antidepressant; antipsychotic; anticonvulsant; immunosuppressant for transplant rejection; antiretroviral; and antineoplastic categories or classes). This directive was aimed at ensuring a smooth transition of the approximately 6 million dual eligible beneficiaries who were converting from Medicaid drug coverage to Medicare drug coverage at the start of the Part D program.

Although section 1860D–11(i) of the Act prohibits us from establishing a “national formulary,” we have interpreted our obligation under section 1860D–11(e)(2)(D)(i) of the Act not to approve discriminatory benefit designs as providing the authority to set standards for review of formularies. In developing our formulary policy, we have sought to build on a careful balance between ensuring access to drugs for vulnerable populations, while at the same time allowing Part D sponsors the ability to implement drug utilization management processes to achieve cost containment. These standards are contained in Chapter 6 of the Medicare Prescription Drug Benefit Manual located at <http://www.cms.hhs.gov/PrescriptionDrugCovContra/downloads/R2PDBv2.pdf>.

Section 176 of MIPPA added a new section 1860D–4(b)(3)(G)(i) to the Act requiring, effective plan year 2010, that the Secretary establish certain categories or classes of drugs that meet two specific statutory specifications: (1) Restricted access to the drugs in the category or class would have major or life threatening clinical consequences for individuals who have a disease or disorder treated by drugs in such category or class; and (2) There is a significant need for such individuals to have access to multiple drugs within a category or class due to unique chemical

actions and pharmacological effects of the drugs within a category or class. In addition, the MIPPA provides the Secretary with the discretion to establish exceptions permitting Part D sponsors to exclude from their formularies, or to otherwise limit access to (including utilization management restrictions or prior authorization), certain Part D drugs from the protected categories and classes.

In the January 16, 2009 **Federal Register** (74 FR 2881), we published the Medicare Advantage and Prescription Drug Programs MIPPA Drug Formulary and Protected Classes Policies interim final rule with comment period that revised the regulations governing the Medicare Part D formularies as a result of MIPPA. We codified the MIPPA provision requiring the inclusion of all drugs from identified “protected categories and classes” on Part D sponsor formularies at § 423.120(b)(2)(v). We also noted in the preamble of the January 16, 2009 IFC that the timing of Part D formulary submissions for 2010 will preclude us from making identification in time for the 2010 contract year. As such, we noted that Part D sponsors must continue to provide coverage of the six classes of clinical concern in contract year 2010, consistent with the policy already in place since 2005. For contract years 2011 and subsequent contract years, we indicated in the preamble that we plan to conduct a comprehensive analysis to—

- Determine which categories and classes of drugs, including which existing six classes of clinical concern, meet the MIPPA requirements for protected categories and classes; and
- Identify any potential exceptions to the requirement that all drugs from protected categories or classes be included on Part D sponsor formularies.

We also specifically noted in the preamble that we are planning a multilevel review process to identify protected categories and classes that would include the following:

- An initial data-driven analysis of widely used treatment guidelines and Part D utilization data; and

- A secondary review by a clinical review panel that will serve to validate the findings of the initial analysis.

We also stated that the second-level expert panel would be “consensus driven” and that “information regarding the independence, potential conflicts of interest, expertise, and balance of the individuals chosen for this panel would be made publicly available.”

We received 30 public comments on the January 16, 2009 IFC. Some commenters suggested an expansion of the current six classes of clinical concern policy, either through the removal of current exceptions or through processes that might broaden the number of protected classes beyond six. Other commenters suggested that the MIPPA was passed in order to codify the current six classes of clinical concern. Still other commenters suggested limiting the protected classes, stating that plans and pharmaceutical benefit managers can only limit beneficiary cost increases through use of formulary and drug utilization management tools. These commenters stated that CMS must carefully weigh increased beneficiary costs against any additional protections that derive from the establishment protected drug classes. Several commenters requested further clarification of terms, such as what we meant by our review of “widely used treatment guidelines” and what is meant by the MIPPA definition of “access to multiple drugs,” with many suggesting different interpretations. Finally, many commenters focused on our process outlined in the January 2009 IFC, with some questioning whether members of the validation review panel would be solicited from experts outside the government under a Federal Advisory Committee Act (FACA) process, whether the representation would include the perspective of beneficiaries, especially groups that advocate for beneficiaries living with specific diseases prevalent among Medicare beneficiaries, and whether the panel would include practicing physicians and specialists with documented

experience in treating Medicare patients in the therapeutic areas under review.

Based on the comments received on the January 16, 2009 IFC, we have decided to revisit section 176 of MIPPA and the “protected classes” for further interpretation and review. While some commenters and a few outside parties have suggested that the Congress’ intention behind section 176 of MIPPA was to codify our preexisting “6 class” policy, we do not believe that the plain reading of the statute supports such an interpretation because the six classes are not expressly identified in the MIPPA. Rather, we continue to believe that various analyses are needed to determine which drug classes meet the MIPPA criteria. Furthermore, varied and conflicting public comments we received on the January 16, 2009 IFC persuade us that the MIPPA criteria are not self implementing and, moreover, the process envisioned in the January 16, 2009 IFC may be unduly burdensome and too unwieldy to permit timely changes in reaction to medical and pharmacological advances. As a result, we are engaging in notice and comment rulemaking to further interpret section 176 of MIPPA.

We believe that the critical policy decision at hand, based on the comments received, is how broadly or narrowly we interpret specific terms in the MIPPA provisions. Interpreted broadly, the provisions in section 176 of MIPPA might easily encompass many classes of drugs and significantly increase costs to the Part D program by eliminating the need for manufacturers to aggressively rebate their products for formulary placement. However, a narrow interpretation of these criteria would reduce the number of classes that are “protected”.

We believe that the plain reading of section 176 of MIPPA does not remove or otherwise revise our transition and coverage determination protections outlined in subparts C and M of part 423, and further explained in Chapters 6 and 18 of the Medicare Prescription Drug Benefit Manual at http://www.cms.hhs.gov/PrescriptionDrugCovContra/12_PartDManuals.asp#TopOfPage. These existing protections require Part D sponsors to establish a transition process, consistent with our requirements (which we propose to codify elsewhere in this rule), for issues associated with coverage of non-formulary drugs. They also require a Part D sponsor to establish an exceptions and appeals process, including an expedited request process in urgent situations that allows a beneficiary the right to request a

coverage determination for a non-formulary Part D drug on the basis of medical necessity. Our requirements further include the right of review of a sponsor’s negative determination by an independent review entity in cases of both a standard and expedited appeal.

We believe that it is critically important that section 176 of MIPPA be read in the context of the other protections inherent in the Part D program in order to avoid establishing unnecessary duplicative protections. The current protections already serve as an underlying foundation to ensuring access to needed Part D drugs that do not appear on a Part D plan’s formulary. We therefore propose to amend the regulatory language at § 423.120(b)(2)(v) that was added by the January 16, 2009 IFC in order to reflect the MIPPA protected categories and classes provision in the context of these protections. Specifically, we are proposing to interpret several of the statutory terms in section 176 of MIPPA to better define the scope of the protections under this section of MIPPA. To that end, we are proposing several new definitions at § 423.100.

In order to read section 176 of MIPPA in the context of the existing Part D program, we believe there is a need to interpret the meaning of the term “restricted access” under the first MIPPA criterion in section 1860D–4(b)(3)(G)(i) of the Act, which refers to “restricted access to the drugs in the category or class [having] a major or life threatening clinical consequences for individuals who have a disease or disorder treated by drugs in such category or class.” In theory, lack of access to any drug that is *medically necessary* could result in serious or life-threatening clinical consequences. Thus, one could argue that all prescribed Part D drugs are medically necessary and therefore should be protected. However, we believe that is more appropriate to interpret the MIPPA criteria more narrowly, both to avoid duplicative protections, as mentioned above, as well as to preserve one of the key aspects of the Part D program—namely, that Part D sponsors have the ability to undertake cost containment efforts through formulary design. For this reason, we believe it makes sense to interpret the statutory criteria that will be used to identify protected categories or classes of drugs with these parameters in mind, while seeking to ensure that the protections afforded under section 176 of MIPPA are meaningful. Under this interpretation, therefore, we intend the criteria to apply in those circumstances wherein a short time delay that results from the

application of existing procedures will result in the exacerbation of the enrollee’s underlying disease to an extent that it would cause persistent or permanent damage. For example, a short delay in access to an immunosuppressant to prevent transplant rejection would be more likely to meet the statutory criteria than a short delay in access to a drug intended to increase bone density or treat hyperlipidemia.

Given these considerations, we believe that in light of existing beneficiary protections under Part D, “restricted access” should be construed to occur in the case of someone who, but for the protected classes provision, urgently requires a Part D drug but is waiting for an expedited redetermination by a Part D plan or our independent review entity with respect to coverage of that drug. It is during this period of time—where the beneficiary may urgently need the drug but does not yet have access to it—that is most likely to result in a major or life threatening clinical consequence for beneficiaries who require treatment of a chronic condition or disease and who are going without such medications while awaiting the redetermination. Accordingly, we believe that we must identify drug classes and categories to, in part, address this situation.

To understand how our proposed definition of restricted access fits in context with the rest of the first MIPPA criterion, we believe it is important to have a consistent interpretation of the phrase “major or life threatening clinical consequences.” In thinking about how to define this term, we considered a definition developed by the FDA for new drug and biological products that are being studied for their safety and effectiveness in treating life-threatening or severely debilitating diseases. The definition of *life-threatening* in that context reads as: (1) Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted; and (2) diseases or conditions with potentially fatal outcomes, where the endpoint of clinical trial analysis is survival (21 CFR 312.81(a)). However, we concluded that this definition is too restrictive for our purposes. Section 176 of MIPPA contemplates ensuring enrollee access to drugs where restricted access “would have *major or life threatening clinical consequences*” (emphasis added). Thus, an interpretation that potentially could exclude “major” clinical consequences that were non-life-threatening would be insufficient. Instead, we believe that the definition of a similar term, “serious

reaction,” found at World Health Organization’s Web site at http://www.who.int/medicines/areas/quality_safety/safety_efficacy/Annex1GlossaryofTerms.pdf is more instructive and more appropriate for addressing the circumstances in which Part D enrollees may face restricted access to medically necessary drugs without a protected class requirement because unlike the FDA definition, it is not limited life-threatening situations, but rather encompasses both major and life-threatening clinical consequences. Therefore, we propose to define major or life threatening clinical consequences in a manner similar to the WHO definition. Specifically, we propose to define “major or life threatening clinical consequences” to mean serious clinical events that arise as a result of not taking a drug that leads to patient hospitalization, or a persistent or significant disability or incapacity, or that result in death.

We note that our proposed definitions with respect to the first criterion of section 176 of MIPPA are intended to provide protection against major or life threatening consequences at a time when other beneficiary protections still would result in a delay in access. We believe that only categories or classes of drugs for which a delay could cause a major or life threatening clinical consequences based on the definitions described above establish the most logical standard for the Part D program given existing beneficiary protections while avoiding potential increased program costs associated with adding duplicative protections.

The second MIPPA criterion requires that “[t]here is a significant need for such individuals to have access to multiple drugs within a category or class due to unique chemical actions and pharmacological effects of the drugs within the category or class, such as drugs used in the treatment of cancer.” To understand how this criterion intersects with the first criterion, one has to understand the meaning of the phrase “significant need for access to multiple drugs.” We believe that this phrase can be interpreted in only two ways: (1) To infer that the statutory phrase means simultaneous use of multiple drugs; or (2) to infer that the phrase means the sequential use of drugs due to a significant likelihood of failure of a specific drug in a class leading to the substitution of another drug or drugs in the same class. To ensure beneficiary protection, we propose to define the term “significant need for access to multiple drugs” to include both readings. Thus, we

propose to define the term to mean instances in which—

- There is a need for simultaneous use of multiple drugs within a drug grouping because such drugs work in combination with each other; or
- There is a strong likelihood of sequential use of drugs within a class or category within a short period of time due to a significant likelihood of failure of a specific drug in a class leading to the substitution of another drug or drugs in the same class. In other words, there is a strong likelihood that a different drug in the same category or class will be needed in a short period of time if the first drug failed due to the unique effects that the drug type may have on an individual. For example, there is a strong likelihood that noncurative chemotherapy will require multiple different drug substitutions as the cancer goes in and out of remission. Second, with respect to duration, we propose that a “short period of time” is a short time frame delay that will result in exacerbation of underlying disease to an extent that persistent and permanent damages will occur.

We propose to define the term “multiple drugs” to mean two or more drugs, and we propose to define the phrase “category or class” for purposes of determining compliance with the rules for protected categories and classes of section 176 of MIPPA as the identification of a drug grouping that is reasonable to identify the applicable drug product. We do not believe this identification is necessarily tied to a specific drug classification system, but rather represents the most specific grouping that is reasonable to identify the applicable drug products. For example, it may include drug groupings based on the USP Model Guidelines, the American Hospital Formulary Service (AHFS) classification, another drug classification system, or some combination thereof to define reasonable groupings of drugs.

Finally, consistent with the statutory authority for the Secretary to identify exceptions to the provision in section 176 of MIPPA, we propose to specify some of the exceptions to the MIPPA provision to include on formulary “all” Part D drugs meeting the two conditions set forth in section 1860D–4(b)(3)(G)(i) of the Act. As we stated in the January 16, 2009 IFC (74 FR 2881) and in our January 28, 2005 Part D final rule (70 FR 4260), inclusion of “all covered Part D drugs” on formulary from a protected class or category does not extend to inclusion of all brand-name drugs and generic versions of the covered drug in question. Under our longstanding interpretation of the term “covered Part

D drug,” and based upon scientific evidence and medical standards of practice, Part D sponsors will only be required to include on their formularies all chemically distinct drugs from the protected classes or categories in order to meet the provision in section 176 of MIPPA. Thus, two drug products that are determined to be therapeutic equivalents by the FDA and identified as such in the FDA’s Orange Book are considered to be the same Part D “drug” and would not be required on all formularies.

We also believe that it is important to consider safety and general drug and population applicability issues in the context of the new protections under section 176 of MIPPA. Although, as noted above, we believe that section 176 of MIPPA is intended to provide additional beneficiary protections, we believe it would be imprudent to interpret these new protections in such a way that they interfere with existing protections intended to promote safety and efficacy. For example, we believe that it is appropriate for Part D sponsors to establish edits for safety and that our policies not interfere with basic drug utilization management edits that sponsors apply at point-of-sale to ensure that adverse events do not occur. Such edits must be consistent with FDA labeling to ensure that they are based on scientific evidence and medical standards of practice. Indeed, we believe that any interpretation of section 176 of MIPPA that interferes with a plan’s ability to impose safety edits would defeat the very purpose of section 176 of MIPPA.

In order to minimize confusion about the scope of the protections under section 176 of MIPPA, we clarify that the formulary requirements set forth in section 1860D–4(b)(3)(G)(ii) of the Act apply only to Part D drugs; therefore, drugs that are not Part D drugs need not be included on a plan’s formulary, even if a particular non-Part-D drug might otherwise be included in a protected class or category under section 176 of MIPPA. In other words, the MIPPA protections do not apply to non-Part D drugs and their exclusion from the formulary requirements is not based on our exceptions authority under section 1860D–4(b)(3)(G)(iii) of the Act. Further, we do not require now as part of our six class policy, and would not require under the authority of section 176 of MIPPA, the inclusion of drugs that have been historically paid for under Part B (for example, “incident to” drugs supplied and administered by physicians during patient visit and paid for under Part B) or whose regulatory status under the definition of a Part D

drug at § 423.100 is not known. Given the fact that these drugs are not covered under Part D today, we believe their lack of presence on plan formularies would not disrupt access. We further believe that requiring the inclusion of these drugs on the formulary when they are not payable under Part D would lead to beneficiary confusion, particularly with respect to drugs with an unknown approval status. For these reasons, we are proposing to exclude drugs with very limited applicability to the Medicare Part D population and non-Part D drugs from the formulary requirements under section 176 of MIPPA.

Therefore, we have added a new paragraph to § 423.120(b)(2) to clarify exceptions to the inclusion of all drugs meeting the criteria under section 176 of MIPPA. Under § 423.120(b)(2)(vi), exceptions would include the following:

- Drug products that are determined to be therapeutic equivalents under the FDA's Orange Book;
- Edits that limit the quantity of drugs due to safety; and
- Other drugs that we may specify through a process that is based upon scientific evidence and medical standards of practice (and, in the case of antiretroviral medications, is consistent with the Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents) and which permits public notice and comment.

We welcome comment on these proposed definitions and clarifications.

As noted previously, we now believe that the process outlined in the January 16, 2009 IFC may be too burdensome to pursue. One practical concern with that process is one of timing. We no longer consider it feasible by contract year 2011 to complete the process outlined in the January 16, 2009 IFC, in which we would—(1) contract with an organization to complete a data-driven analysis to identify possible protected classes and exceptions under the MIPPA; (2) decide on the composition, independence, expertise, potential conflicts of interest, and balance of individuals chosen to participate in the second-level validation panel that would arrive a consensus-driven set of recommendations; and (3) complete notice-and-comment rulemaking to both identify the protected categories or classes and to establish exceptions. Additionally, periodic updates and adjustments to the protected categories and classes, as well as to the exceptions, would take longer to implement if the process contemplated in the preamble

were followed every year or some periodic timeframe thereafter.

We continue to believe that the best way to determine which drug classes meet the MIPPA criteria is through a data-driven process, which includes an analysis of prescription drug event data, a review of widely used treatment guidelines, validation of the results by an expert committee of clinicians, and acceptance by the Secretary. By widely used treatment guidelines, we mean clinical literature that we consider to represent best practices. We envision these would include references in such sources as the Cochrane database and the AHRQ National Guideline Clearinghouse (NGC), and to include literature referred to in the Part D statutory compendia. (For more information on the Cochrane database and the NGC are see their Web sites at <http://www.cochrane.org/reviews> and <http://www.guideline.gov/>, respectively.) Therefore, it is our expectation that we will undertake the following multilevel process, which we again state is critical to any future identification of protected formulary classes under the Part D program:

- Commence an initial data-driven analysis of widely used treatment guidelines and Part D utilization data to identify the following:
 - ++ Possible categories and classes of drugs, including those of the existing six classes of clinical concern, that meet the requirements for protected categories and classes; and
 - ++ Any potential exceptions to the requirement that all drugs from protected categories or classes be included on Part D sponsor formularies.

We note that a review of treatment guidelines along with the review of the prescription drug event data will provide us with the necessary data to make informed decisions on the identification of MIPPA protected classes to present to the Secretary.

- Arrange for a secondary review by a group of government clinicians that will serve to validate the findings of the initial analysis. We believe that an expert Government panel will best assist us in appropriately weighing the data derived from the initial analysis against the statutory requirements to identify protected categories or classes of drugs in which “access to multiple drugs within a category or class” is needed because “major or life threatening clinical consequences” may arise if access is restricted. Furthermore, we believe the expert panel will be well positioned to consider the data that may suggest possible exceptions and consider this data in light of the protected categories or classes in order

to identify exceptions that are based upon available scientific evidence and medical standards of practice. Moreover, an expert panel of government physicians and pharmacists will obviate any problems surrounding independence of clinical judgment and potential conflicts of interest.

- Present recommendations to the Secretary of HHS of the drug classes or categories, and any recommended exceptions.

We note that the main difference between these data-driven process described here and the process outlined in the January 16, 2009 IFC is the composition of the clinical committee that will serve a validation review. As we noted above, an expert panel composed solely of government physicians and pharmacists would obviate any problems surrounding independence of clinical judgment and potential conflicts of interest, and would simplify the process compared to an external panel commissioned under the FACA.

With regard to the designation of the drug classes themselves and the manner in which they are announced, we believe there are two options and solicit comment on which option the public believes will allow us to make timely determinations in a transparent manner.

Option 1: Announce protected classes through subregulatory guidance (for example, the Call Letter) that provides a notice and comment process but does not entail full notice and comment rulemaking.

One option would be to promulgate regulations that set forth the criteria we would use to identify the protected classes and to apply those criteria as part of the data analysis and validation process described above, but to announce the protected classes that result from this process through subregulatory guidance, such as CMS's annual Call Letter to Part D plans, or alternatively through a separate **Federal Register** notice. Under either vehicle, we would invite comment prior to the final announcement of the protected classes and exceptions thereto, and prior to finalizing any changes to the protected classes or exceptions. We believe this approach represents a more simplified and streamlined process. We further believe that this simplified and streamlined process would provide ample opportunity for public input and adequate protection of the public interest in the determination of the protected classes and any exceptions thereto.

Furthermore, we believe that this process also is consistent with other processes we use to make similar

determinations. For example, under Medicare Part B, coverage of off-label use of anticancer therapies may include uses that are supported by certain drug compendia. In the CY 2008 Medicare Physician Fee Schedule final rule, we implemented a new process to make changes to the list of Part B-accepted compendia. This process involves posting materials on the CMS website, soliciting comment, and announcing final decision through nonregulatory means.

Option 2—Announce the protected classes through formal notice and comment rulemaking.

A second option would be to undertake the clinical and data driven review process described above and after promulgating regulations addressing the criteria for identifying the protected classes, implement the proposed protected classes themselves through notice and comment rulemaking, consistent with our proposal in the January 16, 2009 IFC.

We welcome comments on these two approaches for soliciting public comment and announcing the protected categories or classes of drugs required for inclusion on Part D sponsor formularies. We note that, given the implementation timeframes discussed above, as well as the need to ensure consistency in formulary coverage as we complete our analysis to implement the requirements of section 1860D–4(b)(3)(G)(i) of the Act, we will retain our existing six classes of clinical concern contained in Chapter 6 of the Medicare Prescription Drug Benefit Manual (section 30.2.5) for contract year 2010. We further note that any decisions with respect to the retention of these classes for the 2011 contract year will be made either through a separate rulemaking that identifies the MIPPA

protected classes and any exceptions thereto and/or as part of the 2011 Call Letter to Part D plans.

2. Pro-rating the Plan Deductible for Part C MSA Enrollments Occurring During an Initial Coverage Election Period (§ 422.103)

Section 1851(a)(2)(B) of the Act establishes Medicare Medical Savings Account (MSA) plans as a type of health insurance plan that combines both a tax advantaged savings account and a high-deductible health insurance policy. Under this MA plan option, Medicare pays the MA organization offering the MA plan the premium amount charged by the organization for a high-deductible insurance policy and the remainder of the MA payment amount is deposited in the enrollee's savings account. If an individual enrolls in such a plan mid-year, a pro-rated share corresponding to the number of months remaining in the calendar year is placed into the individual's savings account. As provided under § 422.103(d), however, beneficiaries newly eligible for Medicare who enroll in MSAs midyear pursuant to an initial coverage election period (ICEP) are currently required to pay a full deductible for the calendar year. For example, an enrollee whose 65th birthday is in May and who chooses to enroll May 1 will be given 8/12ths of the deposit that has been approved for the plan for the year, but this enrollee is required to pay the full deductible approved for the plan for the entire calendar year. An enrollee whose 65th birthday is later in the year could enroll, for example, on September 1 and would receive a pro-rated deposit representing only 4/12ths of the year; however, this enrollee would also be required to pay the full calendar year deductible.

We are proposing to interpret the deductible requirement as implicitly applying only for the number of months in which a beneficiary is enrolled in the MSA plan, and accordingly are proposing to revise § 422.103(d) to allow beneficiaries who enroll during the year as ICEP enrollments to pay only a pro-rated deductible consistent with the pro-rated deposit they receive. This rule would also apply to disabled enrollees under age 65 who become eligible for Medicare during the year. Interested beneficiaries may inquire with potential MSA plans about their options prior to enrollment, and, upon enrollment, would receive a confirmation of enrollment letter that would inform them of both their pro-rated deposit amount and their pro-rated deductible.

G. Changes To Clarify Various Program Participation Requirements

We have worked with sponsoring organizations to implement and operationalize the Medicare Advantage and Prescription Drug Benefit Programs over the past 4 years. As part of this partnership, we have implemented operational and/or policy guidance via HPMS memoranda or manual instruction to assist sponsoring organizations in ensuring the proper and efficient administration of the Part C and D programs. The proposed regulations in this section either clarify existing regulations or implement new requirements consistent with existing policy guidance, to assist sponsoring organizations with attaining the goals envisioned by the Congress when the legislation implementing the Medicare Advantage and Prescription Drug Benefit programs was first passed. These clarifications are detailed in Table 7.

TABLE 7—CLARIFICATIONS OF VARIOUS SPONSOR PROGRAM PARTICIPATION REQUIREMENTS

Provision	Part 422		Part 423	
	Subpart	Section	Subpart	Section
Clarify what we mean by uniform benefits	Subpart C ..	§ 422.100(d)	Subpart C ..	§ 423.104.
Ensure security of personal health information and other personally identifiable information.	Subpart K ..	§ 422.504	Subpart K ..	§ 423.505.
Require plans to report other payer information to support coordination of benefits (COB).	Subpart C ..	§ 422.108	Subpart C ..	§ 423.464.
Visitor/Traveler Benefit under Part C for the Purpose of Extending Enrollment up to 12 Months.	Subpart B ..	§ 422.74	N/A	N/A.
Codify authority to establish (MTM) Program requirements.	N/A	N/A	Subpart D ..	§ 423.153(d).
Clarify Pharmacy & Therapeutics (P&T) Committee requirements.	N/A	N/A	Subpart C ..	§ 423.120.
Generic equivalent disclosure	N/A	N/A	Subpart C ..	§ 423.132.
Application of access standards at application level.	N/A	N/A	Subpart C ..	§ 423.120.
Standard Timeframe for coverage requirements ...	N/A	N/A	Subpart M ..	§ 423.568.
Clarify Novation requirements	N/A	N/A	Subpart L ...	§ 423.551.

TABLE 7—CLARIFICATIONS OF VARIOUS SPONSOR PROGRAM PARTICIPATION REQUIREMENTS—Continued

Provision	Part 422		Part 423	
	Subpart	Section	Subpart	Section
Cost Contract Program revisions: Appeals and Marketing Requirements.	Subpart O ..	§ 417.428	N/A	N/A.
		§ 417.492		
		§ 417.494		
		§ 417.500		
		§ 417.640		

1. Uniform Benefits Under Parts C and D (§ 422.100(d) and § 423.104)

Section 1852(d)(1)(A) of the Act requires a Medicare Advantage (MA) organization offering a plan to select the providers from whom the benefits under the plan are provided so long as the organization makes such benefits available and accessible to each individual electing the plan within the plan's service area with reasonable promptness and in a manner which assures continuity in the provision of benefits. Section 1860D–2(a) of the Act defines qualified prescription drug coverage to mean access to standard or actuarially equivalent prescription drug coverage and access to negotiated prices (in accordance with section 1860D–2(d) of the Act). We codified these sections in our regulations at § 422.100(d) and § 423.104(b).

Both sections currently require that either an MA organization or PDP sponsor offering a plan must offer that plan to all eligible beneficiaries residing in the plan's service area, or for MA organizations, a subset of the plan's service area. We further interpret section 1860D–2(a) of the Act as requiring the provision of uniform premiums and benefits.

We have provided guidance to Part D sponsors on several occasions indicating that varying cost-sharing or premiums, including waiving cost-sharing or premiums, violates the uniform benefit requirements at § 423.104(b) because doing so results in the Part D sponsor's plan not providing uniform premiums and benefits to all eligible beneficiaries within its service area. We have further informed Part D sponsors that their failure to collect cost-sharing at the time the service is provided or to attempt to collect cost-sharing or bill cost-sharing to the appropriate party (either a beneficiary or another payer) after the fact is in violation of the uniform benefit provisions set forth in the current regulation at § 423.104(b).

However, we believe that § 423.104(b) is not clear in regard to the PDP sponsor's imposition of uniform premiums and cost-sharing. Therefore, we propose to revise § 423.104(b) to

mirror the language at § 422.100 to specify that Part D sponsors apply uniform premiums and cost-sharing.

2. Ensuring the Security of Personal Health Information and Other Personally Identifiable Information (§ 422.504 and § 423.505)

In the contract provisions sections of subpart K of parts 422 and 423, we specify that MAOs and Part D sponsors must permit access to their facilities by the Secretary or his or her designee. Access to facilities must be granted in connection with the Secretary's right to evaluate through audit, inspection, or other means MAO and Part D sponsor compliance with Medicare contract requirements, including the quality, appropriateness, and timeliness of services.

We interpret the Secretary's right to audit or inspect compliance with MA and Part D program regulations to include evaluation of compliance with CMS requirements for maintaining the privacy and security of personal health information and other personally identifiable information of Medicare enrollees. In order to clarify our policy that beneficiaries' personal health information and other personally identifiable information must remain secure, we propose to revise § 422.504 and § 423.505 to make this interpretation explicit. In a related change, we propose to clarify that we interpret the term "facilities" to include an MAO's or Part D sponsor's computer or other electronic systems. We would implement these proposed changes at § 422.504(e)(1)(ii) and § 423.505(e)(1)(ii). We are also proposing conforming changes to the contract requirements related to downstream entities at § 422.504(i)(2)(i) and § 423.505(i)(2)(i), respectively. Note that while we do not believe our authority extends to accessing the facilities of downstream entities, we may review systems and computer-generated information from downstream entities for compliance with privacy and security requirements. Such information includes, but is not limited to, backup tapes, print outs of

screen shots, CDs, and similar information.

We encourage the use of computerized and electronic systems by MAOs and Part D sponsors. We are aware, however, of the additional potential for security and privacy breaches in a computerized/electronic context. Our proposed changes are designed to ensure that beneficiaries' protected health information and personally identifiable information associated with their enrollment remain private and secure.

3. Requirement for Sponsoring Organizations Under Parts C and D To Report Other Payer Information to the Coordination of Benefits Contractor (§ 422.108 and § 423.464)

Section 1852(a)(4) of the Act provides that an MA organization may charge or authorize a provider to seek reimbursement for services from a beneficiary or third party to the extent that payment is made secondary under section 1862(b)(2) of the Act. Section 1860D–2(a)(4) of the Act extends the Medicare secondary payer (MSP) procedures applicable to MA organizations under section 1852(a)(4) of the Act to Part D sponsors and their provision of qualified prescription drug coverage. This authority is implemented for MA organizations in § 422.108 and for Medicare PDPs in § 423.462, as well as in CMS manuals.

MA organizations are responsible for identifying payers that are primary to Part C of Medicare, determining the amounts payable by those payers, and for coordinating the benefits the plan offers with the benefits of such payers. Additionally, MA organizations must take into account Part C costs that could have been recovered or avoided due to MSP when determining costs in the base period. MA organizations must account for Part C MSP amounts in one of three ways. MA organizations must—

- Recover from liable third parties;
- Avoid Part C costs by directing providers to bill liable third parties directly; or
- Account for Part C costs that could have been recovered or avoided, but that were actually not recovered or avoided,

by not including them in Part C base period costs.

MA organizations and PDPs are required to follow the same rules regarding—

- Their responsibilities under the MSP statutory and regulatory provisions;
- Collection of payment from insurers, group health plans and large group health plans, the enrollee, or other entities for covered Part D drugs; and
- The interaction of MSP rules with State laws.

Sections 1860D–23 and 1860D–24 of the Act also require a Part D sponsor to coordinate with SPAPs, as well as other drug plans, including Medicaid programs, group health plans, FEHBP, military coverage, and other plans or programs providing prescription drug coverage. To support the required benefit coordination, section 1860D–2(b)(4)(D)(ii) of the Act permits Part D sponsors to request information on third party insurance from beneficiaries. The authority for COB, as well as for information collection from beneficiaries is implemented for prescription drug sponsors in § 423.464 and in the Coordination of Benefits chapter of the Medicare Prescription Drug Benefit Manual.

The growing number of CMS data sharing agreements with other payers has improved the volume and quality of other payer information available to MA organizations and prescription drug sponsors on the COB data file from CMS. New mandatory insurer reporting of MSP group health plan coverage, liability insurance, no-fault insurance and workers' compensation, required by section 111 of the Medicare, Medicaid, and State Children's Health Insurance Program (SCHIP) Extension Act of 2007 (Pub. L. 110–173), will further expand the other payer information available for MA organization and PDP MSP procedures and for Part D sponsor coordination of benefits. (*See* 42 U.S.C. 1395y(b)(7) and (8).) Most insurers will need to report their own coverage already. It is only when an MA organization becomes aware of coverage that is primary to Medicare offered by another insurer that it will need to report under this rule. In addition to these advances, we continue to seek improvements to the quality of the MSP and COB information we report to MA organizations and Part D sponsors. We believe the best means to accomplish this is to rely primarily on the most reliable sources of other coverage information. Based on our experience, these sources tend to be the other insurers.

However, MA organizations and PDP sponsors will on occasion continue to receive information about other coverage from their enrollees, as well as other sources. While our MA program policy does not currently include reporting requirements, Part D subregulatory policy guidance, reflected in section 50.2 of the Coordination of Benefits chapter of the Prescription Drug Benefit Manual, requires that PDP sponsors submit other coverage information that is brought to their attention within 30 days of receipt to the CMS COB Contractor for verification and application of the verified data to our data systems.

Given the importance of the other payer information to MA organization and PDP MSP procedures and for prescription drug program coordination of benefits, we propose to require the reporting of other coverage information in § 422.108 for MA organizations and § 423.462 and § 423.464 for PDP sponsors. Given concerns regarding the quality of the information, we propose to limit the information reported to that which is reported to the sponsor as being inconsistent with existing information on the COB file.

Specifically, we propose to include in regulatory text the requirement that MA organizations and Part D sponsors, upon being notified of credible new information regarding other payers or changes to existing other payer information, report this information to the CMS COB Contractor in accordance with the processes and timeframes established by CMS. By “credible” we mean information that is consistent with conventions for how group health insurance coverage is identified, for instance including the name and address of the insurance company and the policy identification number. We also propose to extend the reporting requirements to MA organizations as they relate to other primary payers. We note that Medicare MA organizations and Part D sponsors should never be reported to CMS as a “primary” payer. In the absence of another (that is, non-Medicare) primary payer, the MA organization or Part D plan is always primary. This is not to say that if an enrollee has primary individual or employer group coverage through the same insurer or organization through which they also have MA or Part D coverage, such primary coverage should not be reported. In fact, such coverage must be reported. However, reporting Medicare itself as primary serves no purpose and merely causes confusion.

The proposed changes described in this section of the proposed rule would impose a new requirement on MA

organizations but would not change current MSP and coordination of benefits policy for the prescription drug program.

4. Visitor/Traveler Benefit Under Part C for the Purpose of Extending Enrollment Up to 12 Months (§ 422.74)

Under our authority to establish special rules for the enrollment of beneficiaries in MA plans at section 1851(b) of the Act, we had previously described in the Medicare Advantage regulations a visitor/traveler (V/T) benefit. Specifically, § 422.74(d)(4)(iii) established an exception to our disenrollment requirements, under which a plan member must be disenrolled when out of the service area for more than 6 months. Under this exception, MA plans may offer their enrollees extended enrollment in the plan when they are out of the plan service area, but within the United States, from 6 to 12 months if the plan covers services other than emergent, urgent, maintenance and post stabilization, and renal dialysis services. Section 422.74(d)(iii) establishes that an MAO can offer a “visitor” or “traveler” type program which would allow its enrollees to remain enrolled in the plan while out of the plan's service area for up to 12 months. We note that Medicare-covered services can only be covered within the United States. Although we stated in the preamble of the Medicare+Choice program; Managed Care Provisions final rule, published in the August 22, 2003 **Federal Register** (68 FR 50848), that the visitor or traveler program must cover “the full range of services available to other members,” we did not specify in regulation text what we intended by “full range of services.”

Given the lack of specificity in our regulations, we have received a number of questions since that time regarding what services must be covered through a V/T program if an MA plan wishes to retain members up to 12 months when those members are residing outside the service area. We propose to amend § 422.74(d)(4)(iii) to specify that an MAO may offer an extended enrollment V/T option under an MA plan if that plan furnishes all plan covered services—that is, Medicare Parts A and B services and all mandatory and optional supplemental benefits—at in-network cost-sharing levels consistent with Medicare access and availability requirements at § 422.112. An MAO offering a V/T benefit under an MA plan must make the option available to all plan enrollees. Specifically, the V/T benefit must be available to all plan enrollees who are temporarily in the

areas where the V/T benefit is offered for the 6–12 months the member is in the area.

5. Medication Therapy Management Programs Under Part D (§ 423.153(d))

Section 1860D–4(c)(1)(c) of the Act requires Part D sponsors to establish Medication Therapy Management programs (MTMP) and section 1860D–4(c)(2) of the Act requires MTMPs to be designed to ensure, with respect to targeted beneficiaries described in section 1860D–4(c)(2)(A)(ii) of the Act, that covered Part D drugs are appropriately used to optimize therapeutic outcomes through improved medication use and to reduce the risk of adverse events. These requirements are codified at § 423.153(d) of the Part D regulations.

Section 423.153(d)(1) requires each Part D sponsor to establish a MTMP that is designed to ensure that covered Part D drugs (as defined in § 423.100) prescribed to targeted beneficiaries are appropriately used to optimize therapeutic outcomes through improved medication use; designed to reduce the risk of adverse events for targeted beneficiaries; furnished by a pharmacist or other qualified provider; and allowed to distinguish between services provided in ambulatory and institutional settings. Section 423.153(d)(2) defines targeted beneficiaries as enrollees who have multiple chronic diseases, are taking multiple Part D drugs, and are likely to incur annual costs for covered Part D drugs that exceed a predetermined level as specified by the Secretary.

In the original Part D final rule (that is, the January 28, 2005 final rule), we did not identify specific medication therapy management (MTM) requirements beyond those contained in the Act because there was insufficient industry experience and no widely accepted standard practices for MTMPs. Moreover, we also believed that in the future outcomes measures would provide the best method for evaluating MTMPs and promoting the most effective programs. However, given the experience garnered from the first few years for the Part D program, and as we still await further development of MTMP outcomes measures that can serve the Part D program, we have determined that it necessary to have more specific Part D MTMP requirements for enrollment methods, targeting procedures, and MTM services. Accordingly, in the 2010 Call Letter, we included policy guidance regarding the implementation of MTMPs. This policy guidance reflects common practices among Part D

MTMPs that were derived from our extensive review of MTMP applications, plan-reported data, exploratory research on MTM, informal interviews with Part D sponsors, and other relevant literature and data. In this rule, we are proposing to codify this policy guidance in § 423.153(d). We believe the proposed changes to the MTMP requirements will promote greater consistency across the Part D program that will allow for better evaluation and comparison of MTMPs when outcomes measures become available.

Specifically, in accordance with sections 1860D–4(c)(1)(C) and 1860D–4(c)(2) of the Act, we propose to add the following requirements:

- Part D sponsors shall use only an opt-out method for MTMP enrollment;
- Part D sponsors shall target beneficiaries for MTMP enrollment at least quarterly during each plan year; and
- Part D sponsors shall offer a minimum level of MTM services for each beneficiary enrolled in the MTMP that includes interventions for both, beneficiaries and prescribers, annual comprehensive medication reviews, and quarterly targeted medication reviews.

In addition, we are proposing to revise the requirements for targeting beneficiaries who have multiple chronic diseases and take multiple Part D drugs by specifying the maximum number of multiple chronic diseases and multiple Part D drugs that Part D sponsors may establish as a minimum threshold for satisfying their MTMP targeting criteria.

We propose adding § 423.153(d)(1)(v) to require Part D sponsors to enroll beneficiaries in their MTMPs using an opt-out method of enrollment only. Under this proposal, a beneficiary that meets the targeting criteria would be auto-enrolled into the MTMP and considered to be enrolled unless the he or she declines enrollment. This opt-out method of enrollment is currently the preferred method of enrollment among Part D sponsors, used by approximately 85 percent of current MTMPs, and has increased enrollment of targeted beneficiaries into MTMPs. As a result, we believe that requiring an opt-out method of enrollment will provide more beneficiaries with access to MTM services.

We also propose adding § 423.153(d)(1)(vi) to require Part D sponsors to target beneficiaries for enrollment in the MTMP at least quarterly during each plan year. Currently, more than 95 percent of Part D sponsors target beneficiaries for enrollment in their MTMPs on a daily, weekly, monthly, or quarterly basis. We believe that making this a requirement

for all Part D sponsors will allow more Medicare beneficiaries to have access to the MTMP earlier in the year. Part D sponsors also can promote continuity of care by identifying current MTMP enrollees towards the end of a plan year who will qualify for MTMP enrollment in the next plan year. This practice would allow the Part D sponsors to have such beneficiaries enrolled in their MTMP at the beginning of the next plan year.

We also propose adding § 423.153(d)(1)(vii) to require Part D sponsors to offer a minimum level of MTM services for each beneficiary enrolled in the MTMP that includes interventions for both beneficiaries and prescribers; annual comprehensive medication reviews; and quarterly targeted medication reviews. In 2008, approximately 90 percent of Part D MTMPs provided interventions targeting both beneficiaries and prescribers. Our proposed requirement that MTMPs include interventions for both beneficiaries and prescribers does not mean, however, that all interventions must target both the beneficiary and the prescriber. Instead, Part D sponsors must determine if the beneficiary, prescriber, or both should be targeted for any specific intervention or interventions. Prescriber interventions may be passive (for example, faxed or mailed) and should be targeted to resolve potential medication-related issues or other opportunities to optimize medication use.

Furthermore, while Part D sponsors may incorporate passive or “lower touch” beneficiary interventions, such as education newsletters, drug utilization review (DUR) edits, refill reminders, and medication lists into their MTMPs, where appropriate, these passive interventions cannot be the sole offerings. Part D sponsors must also offer MTM services to beneficiaries that include an interactive component, continued monitoring, and follow-up when necessary. In addition, Part D sponsors should have procedures in place to follow-up with beneficiaries that do not respond to initial offers for MTM services.

Under this proposal, Part D sponsors would also be required to offer an annual comprehensive medication review (CMR) to all targeted beneficiaries. With the exception of targeted beneficiaries in long-term care settings, the CMR would be required to include an interactive, person-to-person consultation performed by a pharmacist or other qualified provider. A CMR is a review of a beneficiary’s medications including prescription medications,

over-the-counter (OTC) medications, herbal therapies and dietary supplements intended to aid in assessing medication therapy, and optimizing patient outcomes. The review of the beneficiary's medication may be performed concurrently with the beneficiary consultation or prior to the consultation by a qualified provider or computerized clinical algorithm. The consultation must be a real-time interaction that is provided either face-to-face or via an alternative interactive method such as the telephone. Finally, the beneficiary must receive a written summary of the CMR and consultation that may include such things as a medication record, reconciled medication list, action plan, or recommendations for monitoring, education, or self management.

In addition to the annual CMR, under this proposal, Part D sponsors would be required to perform targeted medication reviews for all beneficiaries enrolled in the MTMP no less often than quarterly. These targeted reviews would focus on assessing medication use since the CMR and determining if any issues that were identified during the CMR remain unresolved or if any new drug therapy issues have arisen. The Part D sponsor must assess the findings of these reviews to determine if a follow-up intervention is necessary with either the prescriber or beneficiary. Unlike the CMR, these interventions are not required to be interactive although it should be considered when appropriate.

Consistent with section 1860D-4(c)(2)(ii)(A) of the Act, Part D sponsors must target beneficiaries who have multiple chronic diseases for MTM services. In the original rule, we left the determination of "multiple" and "chronic disease" entirely to the Part D sponsors. In 2008, approximately 85 percent of Part D MTMPs targeted beneficiaries with a minimum of two or three chronic diseases. Based upon our experience with Part D MTMPs since the beginning of the Part D program, we issued guidance in 2009 to clarify the range and types of diseases that will satisfy this requirement beginning in 2010.

In this rule, we propose to revise § 423.153(d)(2)(i) to specify that the minimum number of multiple chronic diseases for targeted beneficiaries be no more than three. Under the proposed revision to § 423.153(d)(2)(i), we would require Part D sponsors to define the minimum threshold for "multiple" for purposes of targeting beneficiaries as no more than three chronic diseases. Therefore, Part D sponsors would be permitted to set their minimum threshold at two or three and target

beneficiaries with at least two chronic diseases or at least three chronic diseases.

Under this proposed revision to § 423.153(d)(2)(i), Part D sponsors may continue to target any chronic diseases or limit MTMP enrollment to enrollees having specific chronic diseases. However, beginning in 2010, CMS guidance specifies, at a minimum, that Part D sponsors should target at least four of seven core chronic diseases that we have identified as prevalent in the Medicare population based upon the analysis of the RxHCC Risk Adjustment model, posing a risk to the Medicare Trust Fund, and reflecting the most common diseases targeted by Part D MTMPs in general. The seven chronic diseases are hypertension, heart failure, diabetes, dyslipidemia, respiratory disease, bone disease-arthritis, and mental health diseases such as depression, schizophrenia, and bipolar disorder. In determining whether a beneficiary meets the minimum number of multiple chronic diseases to be targeted for MTM services, a beneficiary could have any combination of the chronic diseases targeted by the Part D sponsor.

Consistent with section 1860D-4(c)(2)(ii)(II) of the Act, plan sponsors must target beneficiaries taking multiple covered Part D drugs for MTM services. In the original Part D rule, we left the determination of "multiple" entirely to the Part D sponsors. Based upon our experience and extensive analysis of the Part D MTMPs since the beginning of the Part D program, we issued guidance in 2009 to clarify the range that plan sponsors should consider in order to satisfy the statutory requirement beginning in 2010. Specifically, we noted that Part D sponsors should define "multiple" for purposes of satisfying this requirement as no more than eight Part D drugs as the minimum number of multiple Part D drugs. Consistent with this policy guidance, we now propose to revise § 423.153(d)(2)(ii) to specify that no more than eight multiple Part D drugs be established as a minimum for targeted beneficiaries. Therefore, Part D sponsors would be permitted to set this minimum threshold for MTMP eligibility at any number equal to or between two and eight.

Under section 1860D-4(c)(2)(ii)(III) of the Act, plans must target beneficiaries that are likely to incur annual costs for covered Part D drugs that exceed a level specified by CMS. In the 2010 Call Letter, we specified a new, lower three thousand dollar threshold. Moving forward, we believe that it makes more sense to establish a dollar threshold

based upon a benchmark that is tied to the Part D benefit. We believe that the initial coverage limit (ICL) for the Part D defined standard benefit provides a logical benchmark for the MTMP because it ensures that Part D sponsors will always be able to target enrollees at risk of entering the coverage gap. Accordingly, in this rule, we propose to revise § 423.153(d)(2)(iii) to specify that targeted beneficiaries must be likely to incur costs for covered Part D drugs that exceed the ICL for the Part D defined standard benefit for the applicable Part D plan year.

6. Formulary Requirements—Development and Revision by a Pharmacy and Therapeutics Committee (§ 423.120)

Section 1860D-4(b)(3)(A) of the Act requires Part D sponsors to use a pharmacy and therapeutics (P&T) committee to develop and review the formulary if the Part D sponsor uses a formulary. In developing and reviewing the formulary, section 1860D-4(b)(3)(B) of the Act requires the P&T committee to base clinical decisions on the strength of scientific evidence and standards of practice, including accessing peer-reviewed medical literature, such as randomized clinical trials, pharmaco-economic studies, outcomes research data, and on such other information as the committee determines to be appropriate. The P&T committee must also consider whether the inclusion of a particular Part D drug in a formulary or formulary tier has any therapeutic advantages in terms of safety and efficacy. We codified these requirements at § 423.120(b)(1).

In the preamble to the January 28, 2005 final rule (70 FR 4193) and subsequent formulary guidance, we distinguished between the roles of the P&T committee in determining which drugs are placed on a formulary versus the application of utilization management tools that are applied to the drugs placed on the formulary. Specifically, we said that the P&T committee recommendations regarding which Part D drugs are placed on a formulary are binding on the Part D sponsor while recommendations regarding utilization management tools such as prior authorization (PA), step therapy, and quantity limits are advisory only and not binding on the Part D sponsor. We made this distinction because we believed that the placement of a drug on the formulary was the primary clinical decision in developing a formulary while the application of utilization management tools, although clinically justified, required the consideration of additional

financial and benefit design criteria that went beyond the scope of the P&T committee role. Consequently, we believed it was only necessary for the P&T committee to review for clinical appropriateness Part D sponsor policies that guide utilization management processes and codified this requirement in § 423.120(b)(vi).

We have gained a better understanding of the formulary development process since the beginning of the Part D program and now recognize that the application of PA criteria, step therapy, and quantity limits are as important to the clinical soundness of a formulary as the drugs that are included. Access to Part D drugs may be influenced as much by the application of PA criteria, step therapy requirements, or quantity limit restrictions as it can be by exclusion of a Part D drug from a Part D formulary. For example, one formulary could list twice as many drugs as another formulary but if all the additional drugs on the second formulary are subject to PA requirements, overall access to Part D drugs may be the same under both formularies. For this reason, our formulary review process has not been limited to evaluating the number and types of drugs on Part D formularies but also includes the review of the specific PA criteria, step therapy requirements, and quantity limit restrictions that are applied within the Part D formularies. Therefore, in accordance with section 1860D-4(b)(3)(A) and (b)(3)(B) of the Act, we propose adding new paragraph § 423.120(b)(1)(ix) to require Part D P&T committees to review and approve all clinical PA criteria, step therapy protocols, and quantity limit restrictions applied to each covered Part D drug.

PA criteria, step therapy requirements, and quantity limits directly affect beneficiary access to formulary drugs. Because P&T committees must review and approve all drugs before they may be added to a formulary, we also believe it is necessary that all PA criteria, step therapy protocols, and quantity limits be approved by P&T committees prior to their application to formulary drugs. We continue to recognize that the decision to apply such utilization management tools is not based solely upon clinical considerations and, therefore, remains the responsibility of the Part D sponsors. However, we believe this new requirement adds a necessary beneficiary protection by ensuring that independent clinical experts have reviewed and approved each application of these utilization management tools for clinical appropriateness. It is our understanding

that this is standard practice for P&T committees, and therefore, do not believe this requirement creates an additional burden.

Finally, we do not believe it is necessary for P&T committees to review and approve administrative PA criteria such as those used to make “B vs. D” determinations. Only PA criteria that require clinical information and justification require the review and approval of the P&T committee.

7. Generic Equivalent Disclosure Under Part D (§ 423.132)

Section 1860D-4(k)(1) of the Act requires a Part D sponsor to have each of their network pharmacies inform enrollees of any difference between the price of the drug(s) they are purchasing via the plan and the price of the lowest priced therapeutically equivalent generic product available to the pharmacy. Section 1860D-4(k)(2)(A) of the Act requires that this information be provided at the time of purchase except for purchases delivered by mail when it must be provided at the time of delivery. Under section 1860D-4(k)(2)(B) of the Act the Secretary has the authority to waive this requirement for certain entities in certain cases as specified in § 423.132(c).

In § 423.132(d), we specified that for enrollees in long-term care pharmacy settings, the timing portion of the disclosure requirement (that is, the requirement that the enrollee be informed at time of purchase) may be waived. Accordingly, sponsors are required to disclose the differential (if any) in pricing for long-term care network pharmacies by requiring that this information be provided in the explanation of benefits (EOB).

Over time, we have heard from sponsors, as well as pharmaceutical benefit managers on behalf of sponsors, that providing this information in the EOB is unworkable from a plan operational standpoint. Primarily, this is due to the fact that information on generic pricing can—and often does—vary day to day; thus, sponsors cannot accurately reflect the differential within a monthly EOB. Additionally, sponsors have pointed out that they would need to program the generic equivalent prices for all drugs specific to a particular LTC’s contracted reimbursement rate into their systems to populate electronically on the EOB, which represents a significant programming and financial burden.

We also believe the generic equivalent information provided on the EOB is of no value to the long-term care beneficiary. In the LTC setting, the beneficiary receives the medication after

the prescription drug claim has been submitted by the LTC pharmacy and processed by the Part D sponsor. Therefore, the ability of the beneficiary to make changes at the point-of-service based upon information provided on the EOB is simply not feasible. Unlike the enrollee standing at the retail pharmacy counter at time of service, enrollees in long-term care institutions have limited opportunities to affect a switch to a lower-priced generic substitute before dispensing. Because of this limitation, we have not enforced this regulatory requirement and have not included model language that addresses this requirement in the EOB.

For the aforementioned reasons, we are proposing to revise § 423.132(c) by adding long-term care network pharmacies to the list of entities for which from the public disclosure requirement is waived, and revise § 423.132(d) to remove the requirement that long-term care network pharmacies provide the pricing differential information in enrollees’ EOBs.

8. Access to Covered Part D Drugs (§ 423.120)

The statute at sections 1860D-4(b)(1)(C) and 1860D-21(c)(1) of the Act establishes the standards for convenient access for network pharmacies for PDP sponsors and other Part D sponsors. This section of the statute requires that the sponsor of a PDP shall secure the participation in its network of a sufficient number of pharmacies that dispense (other than by mail order) drugs directly to patients to ensure convenient access consistent with the rules established by the Secretary, and as long as they are no less favorable than the TRICARE pharmacy access standards.

A TRICARE contractor is required to maintain a pharmacy network sufficient to meet the following minimum beneficiary access standards on an overall basis—Urban: a pharmacy within 2 miles of 90 percent of the beneficiaries; Suburban: a pharmacy within five miles of 90 percent of the beneficiaries; and Rural: a pharmacy within fifteen miles of 70 percent of the beneficiaries. We adopted into regulation these standards, but instead of specifying them at the contract or PDP sponsor level, erroneously established them at the plan level. Specifically, in § 423.120(a) of the regulation, which describes the requirements to assure pharmacy access, we inadvertently used the term “plans” instead of the correct terminology of PDP sponsor or other Part D sponsors. This error is problematic when considering the definitions outlined in

§ 422.2 (for MA) and § 423.4 (for Part D) because the term “plan” is intended to mean a specific benefit package offered to beneficiaries living in a geographic area. For any given service area, Part D sponsors frequently offer multiple plans under one contract with CMS, and any given plan may be offered within a subset of the Part D sponsor’s total service area.

Our intention has always been to ensure adequate access to Part D covered drugs at sponsor level, not at the plan level. For one, the statute explicitly states that access should be ensured at the PDP sponsor level. Further, assessing adequacy of pharmacy access is one of the most critical steps in the Part D application review process and determining access to Part D covered drugs at the plan level is not possible during application review. This is because plan service areas (potentially subsets of Part D sponsor or organization service areas) are not determined until the time of the bid submission, which occurs after applications are reviewed. However, sponsor service areas are known at the time of application submission. Our proposed correction would align our regulations with the intent of the statute with regard to the level of analysis that should be conducted for access to Part D drugs, namely at the Part D sponsor level, rather than at the plan level.

We note that as a practical matter and consistent with the current drafting of the regulation, if the Part D sponsor’s entire service area is larger than one State, we will continue to ensure access at no greater than the State level for multi-state regions. This approach is necessary to ensure that pharmacies are not unduly clustered in one part of the region. Accordingly, based on the preceding rationale, we are proposing to revise the text of the regulation that discusses pharmacy access in § 423.120(a)(10 through (a)(7) to refer to PDP sponsors, MA organizations offering local and regional MA–PD plans, and cost contracts rather than plans. Additionally, since § 423.120(a) (defining access requirements for Part D drugs) references a definition provided in § 423.112(a) (establishment of PDP service areas), it is necessary to correct the terminology in that location as well. Therefore, we propose to revise § 423.112(a) to specify the establishment of service areas for PDP sponsors.

9. Standard Timeframe and Notice Requirements for Coverage Determinations Under Part D (§ 423.568)

Section 1860D–4(g) of the Act requires Part D plan sponsors to establish procedures for processing

requests for coverage determinations and redeterminations. Those procedures must apply to Part D plan sponsors in the same manner as such requirements apply to MA organizations with respect to organization determinations and reconsiderations. In accordance with section 1860D–4(g) of the Act, § 423.568 establishes the standard timeframe and notice requirements for coverage determinations. However, that section does not explain the method for filing such requests. We originally omitted these instructions from § 423.568 because § 422.568 does not dictate the method for filing requests for standard organization determinations. However, elsewhere in this rule, we are proposing to revise § 422.568 of the MA regulations by adding a new paragraph (a) clarifying the method for filing requests for standard organization determinations. The proposal requires MA organizations to accept standard organization determination requests orally and in writing, except for standard requests for payment, which must be submitted in writing unless the MA organization adopts a voluntary policy of accepting oral payment requests. Because section 1860D–4(g) of the Act requires Part D plan sponsors to meet the requirements for Part D coverage determinations in the same manner as such requirements apply to MA organizations for organization determinations, we propose to make a corresponding change to § 423.568 and require Part D plan sponsors to accept standard coverage determination requests orally and in writing. This proposed change would not apply to standard requests for payment, which must be submitted in writing unless the plan sponsor adopts a policy for accepting those requests orally.

In addition to this technical change, we propose to revise the timeframe for a Part D plan sponsor to notify an enrollee of a payment determination in § 423.568(b). The regulation currently requires that a plan sponsor notify the enrollee of its determination no later than 72 hours after receipt of the request. We propose to revise the provision to require Part D plan sponsors to process requests for payment no later than 14 calendar days after receipt of the request, and also make payment no later than 14 calendar days after receiving the request when a plan sponsor’s decision is partially or fully favorable.

As noted above, section 1860D–4(g) of the Act requires Part D plan sponsors to meet the requirements for Part D coverage determinations in the same manner as such requirements apply to MA organizations with respect to

organization determinations. The MA regulations under § 422.568 distinguish between how requests for benefits not yet received and requests for payment are processed by MA plans. The rules pertaining to requests involving benefits not yet received are contained in paragraph (a), while paragraph (b) contains the rules for processing requests for payment. In accordance with section 1860D–4(g) of the Act, this distinction was carried over to Part D in current § 423.568(a) and (b).

We received a comment on the Application of Certain Appeals Provisions to the Medicare Prescription Drug Appeals Process proposed rule (73 FR 14342), published in the March 17, 2008 **Federal Register**, recommending that we revise § 423.568(b) of the existing regulations by lengthening the timeframe for making standard coverage determinations involving requests for reimbursement submitted by enrollees. Although the comment was outside the scope of the Part D appeals-related proposals in the March 17, 2008 proposed rule, we believe the commenter’s suggestion merits consideration, as discussed in detail below.

The commenter contends that the existing 72-hour requirement for making a determination on an enrollee’s request for reimbursement constitutes an unprecedented and overly burdensome timeframe, and the only way a Part D plan sponsor can meet the regulatory timeframe is by making an adverse coverage determination (that is, deny the request for payment). Thus, the existing requirement in effect forces an enrollee into the Part D appeals process, even though in the vast majority of such situations, the claim will eventually be paid within the 30-day timeframe for effectuating a coverage determination. The commenter recommended that we revise § 423.568(b) to extend the timeframe for making a coverage determination on a request for payment from 72 hours to 30 days.

As the commenter indicates, § 423.568(b) sets forth the coverage determination and notification requirements in situations (generally involving non-network pharmacies) where an enrollee has already obtained a drug and subsequently makes a request to the Part D plan sponsor for payment. Existing § 423.568(b) requires a Part D plan sponsor to make this coverage determination and notify the enrollee of its determination no later than 72 hours after receiving such a payment request. Although the regulations do not specify a timeframe for making payment to the enrollee when the plan determines the drug in

question should be covered, plans are directed by manual guidance that such payment should be made within 30 days of the request. We note that the 30-day effectuation timeframe comports with the established requirements in § 423.636 for effectuating redeterminations or reconsiderations involving requests for payment. It also generally parallels the prompt payment provisions that apply under § 422.520 and § 422.568 of the MA program.

The intent of these provisions was to ensure enrollees receive a prompt response to requests for payment while still giving plans a reasonable amount of time to process the payment. However, in practice, we agree that the 72-hour timeframe for making a coverage determination in these situations may be quite difficult for Part D plan sponsors to meet. Requests for reimbursement are generally submitted by mail in paper form, and must be identified as reimbursement requests, transferred from the mailroom to the reimbursement processing department, and then manually entered and adjudicated by Part D plan sponsors outside of the usual online real-time electronic claims processing procedures. We also note that under these circumstances, information that Part D plan sponsors need to make meaningful determinations with respect to a request (which is readily available on electronic claims) may be missing from the member-submitted paper claim. Finally, the Part D plan sponsor must notify the enrollee of its determination within 72 hours. Thus, as the commenter asserts, in practice the only way to meet the 72-hour coverage determination timeframe often may be to make a negative coverage determination, at least initially, which is clearly not in the best interests of the enrollee. This initial negative determination can be particularly confusing to an enrollee in situations where a Part D plan sponsor subsequently determines that the reimbursement request should be paid and remits payment to the enrollee, frequently within a few days of the initial negative determination.

As previously stated, the current regulations do not establish a timeframe for effectuating payment, and our manual guidance establishes a 30-day timeframe for doing so. Thus, even when a Part D plan sponsor completes the process above and issues a coverage determination within 72 hours, it is under no obligation to make payment any sooner than 30 calendar days after receiving the request. While we recognize that receiving Part D coverage decisions as soon as possible is important, an enrollee who is requesting

reimbursement already has the needed prescription drug in hand. Thus, we believe it is more important for him or her to receive the actual payment as soon as possible, rather than simply a determination as to whether payment will or will not be made.

Therefore, we believe it would be in the best interests of enrollees to modify the requirements of § 423.568(b) by extending the timeframe for making coverage determinations with respect to requests for payment in such a way as to avoid confusion but also ensure that enrollees receive payment as soon as possible. Based on our experience and previous discussions with Part D plan sponsors, we have determined that Part D sponsors generally are capable of making such payments within a 14-day period following receipt of a reimbursement request, as opposed to the 30-day period recommended by the commenter. Therefore, we propose revising § 423.568(b) to require Part D plan sponsors to take the following actions: (1) Make a coverage determination on a request for payment and notify the enrollee of its determination no later than 14 calendar days after receipt of a request for reimbursement, and (2) for favorable coverage determinations, make payment no later than 14 calendar days after receipt of the reimbursement request. We believe these changes will establish a more reasonable standard for the adjudication of paper claims, as well as ensure faster payments to enrollees who submit these requests. Thus, this change will better serve both plans and their members. As a result of changes proposed elsewhere in this rule, if adopted, these new requirements regarding the timeframe for processing requests for payment would appear at § 423.568(c) of the regulations.

Our last proposed change to § 423.568 involves adding new paragraphs (d) and (e), which will explain the form and content of favorable coverage determination decisions. In § 423.568(d), we propose requiring plan sponsors to send written notice of fully favorable decisions to enrollees. We also propose to allow plan sponsors the option of providing the initial notice orally so long as a written follow-up notice is sent to within 3 calendar days of the oral notification. In § 423.568(e), we propose to require notice of fully favorable decisions to include the conditions of the approval in a readable and understandable manner.

Adding further requirements regarding the form and content of favorable determination decisions to the Part D regulations is necessary because prescription drugs are often provided to

beneficiaries on a recurring basis (unlike most MA services which are generally provided to beneficiaries only once), and requiring plans to provide the terms of an approval in writing helps ensure continuity of care for Medicare beneficiaries who receive prescription drugs under Part D. The prescription may be subject to prior authorization or some other rule which needs to be met before a prescription can be refilled. Also, a prescription may only be approved for a specific period of time and refills may not be authorized. In those situations, it is important for the enrollee to know the conditions (for example, duration, limitations, and coverage rules for refills) of the approval before he or she needs to refill the prescription, so he or she can work with his or her physician to secure prior approval for additional refills, obtain an exception, or switch to an appropriate alternative prescription if necessary. Otherwise, the enrollee may experience a break in coverage if he or she attempts to fill a prescription and is told for the first time at the pharmacy that the prescription cannot be filled because it is subject to a coverage rule or additional refills have not been authorized. We believe the proposed changes to the notice requirements for favorable coverage determinations will help to ensure that enrollees and their physicians or other prescribers have the information they need in order maintain the continuity of prescription drug treatment.

10. Expediting Certain Coverage Determinations (§ 423.570)

Consistent with the proposed revisions to § 423.568, we propose to make a technical change to § 423.570 by revising the cross reference to § 423.568(a) to § 423.568(b).

11. Timeframes and Notice Requirements for Expedited Coverage Determinations (§ 423.572)

In accordance with section 1860D-4(g) of the Act, § 423.572 establishes the timeframe and notice requirements for expedited coverage determinations. Section 423.572(c)(1) requires Part D plan sponsors to include the specific reasons for any expedited decision (whether favorable or adverse) in its decision notice, and paragraph (c)(2) addresses the content of adverse decision notices. However, § 423.572 does not include any content requirements for favorable expedited decisions. Consistent with our rationale for adding form and content requirements for favorable standard coverage determination decisions, we believe form and content requirements

for favorable expedited coverage determinations are important beneficiary protections that will help to ensure that enrollees are able to maintain continuity in their prescription drug treatment. Therefore, we propose to revise § 423.572(b) by requiring plan sponsors to send written notice of fully favorable expedited decisions to enrollees, and allowing plan sponsors the option of providing the initial notice orally so long as a written follow-up notice is sent to the enrollee within three calendar days of the oral notification. We also propose to add paragraph (c)(2), which requires notice of a fully favorable expedited decision to provide the conditions of the approval in a readable and understandable manner.

We are also proposing in § 423.572(c)(2)(i) to require plan sponsors to issue adverse expedited coverage determination decisions using CMS approved language in readable and understandable form. Section 423.568(d) requires plan sponsors to use approved notices for adverse standard coverage determinations, and a parallel instruction for adverse standard and expedited coverage determinations is contained in subregulatory guidance. We developed Form CMS-10146 for use when plan sponsors issue adverse coverage determinations and, in our subregulatory guidance, we instruct plan sponsors to use that form when issuing adverse standard and expedited coverage determination decisions. Our proposed change in § 423.572(c)(2)(i) would reconcile this discrepancy in the regulations. We note that the proposed change does not create an additional burden for plan sponsors because sponsors already submit Form CMS-10146 to CMS for approval for adverse standard coverage determination decisions and, consistent with our subregulatory guidance, we expect plan sponsors to also use Form CMS-10146 for adverse expedited coverage determination decisions.

12. Clarify Novation Agreements Under Part D (§ 423.551)

Section 1860D-12(b) (1) of the Act provides the Secretary with the authority to enter into contracts with PDP sponsors. Additionally, section 1860D-12(b)(3)(B) of the Act grants the Secretary the authority to amend or modify these contracts in accordance with the furtherance of the purpose of the Act.

Consistent with the above-stated authority, we have implemented contracting regulations including § 423.551 of the Part D regulations, which provide for the novation of a PDP

sponsor contract in the event of a change of ownership involving a PDP sponsor. A change of ownership prompting the execution of a novation agreement is appropriate when a PDP sponsor is acquired or when it no longer can or wants to continue to participate in the PDP program. In the latter instance, a change of ownership can provide both the holder of the contract and CMS with an opportunity to transfer the ownership of the contract to a different entity with little or no disruption to the enrolled beneficiaries when the original entity faces difficulties (for example, financial, administrative) in operating its PDP contract. A change in ownership of the PDP line of business, which is recognized by CMS when we agree to a novation of the existing PDP sponsor contract, in this instance promotes the efficient and effective administration of the PDP program.

However, over the past few years several PDP sponsors have requested CMS approval of transactions that involve the sale of a piece of the sponsor's contract with CMS or less than the full line of PDP business [all PDP contracts held by that PDP sponsor]. For example, several PDP sponsors who have missed the LIS benchmark for a particular region requested to novate that portion of their contract to another PDP who met the benchmark in the region.

However, our policy goals are not served when a sponsor is simply using the novation process to pick and choose which markets it wishes to serve at any given time and to profit from its exit from a given PDP region when a simple nonrenewal for that region is an option available to the sponsor. Novations are not intended to be an instrument for moving LIS beneficiaries when a particular sponsor has missed the benchmark. Rather, we have a reassignment process for moving LIS beneficiaries to sponsors who have met benchmark for the new contract year.

Accordingly, we propose to revise § 423.551 and add new paragraph § 423.551(g) to restrict the situations in which we will agree to a PDP sponsor contract novation to those transfers involving the selling of the sponsor's entire line of PDP business, which would include all PDP sponsor contracts held by the legal entity. We believe that allowing the spin-off of just one contract (when the PDP sponsor has more than one PDP contract) or pieces of a single contract can have a negative impact on beneficiary election rights.

We are recommending becoming more prescriptive in this area because our experience gained over the first 4 years

of the program indicates this is necessary for the reasons stated above. The proposed change would also create consistency between the MA program and the PDP program, because the MA program only allows novations that include the entire MA line of business (that is, all MA contracts held by a single legal entity). We invite comments from sponsors and the industry about this proposed change, and suggestions on other options which would accomplish the same policy goals.

13. Cost Contract Program Revisions: Appeals and Marketing Requirements (§ 417.428, § 417.494, § 417.500, and § 417.640)

Although the cost contract program authorized under section 1876 of the Act and the health care prepayment plan (HCPP) programs authorized under section 1833 of the Act are based on reasonable costs, these programs have important elements in common with the MA program. As in the case of MA coordinated care plans, and unlike original Medicare, cost contractors authorized under section 1876 of the Act and HCPPs employ networks of providers and deliver services through a managed care model. However, unlike MA plans, enrollees under cost contracts authorized under section 1876 of the Act and HCPPs are not "locked in" to their plans networks, and can always receive any service through Original Medicare if they pay original Medicare cost sharing.

In the case of cost contracts authorized under section 1876 of the Act, the MA statute specifically recognized the parallels between contracts authorized under section 1876 of the Act and MA contracts, providing in section 1856(b)(2) of the Act that MA standards "shall be based on standards established under section 1876 to carry out analogous provisions of such section." Indeed, many of the original Part C regulations borrowed wholesale from the provisions in section 1876 of the Act and codified in Part 417. Using already established programs as the basis for new but related programs is common practice, one of the most recent examples of which is the Part D prescription drug benefit program. The MMA directed that fundamental aspects of the program, such as enrollment and payment policies, be similar to those of the MA program.

There are several MA program requirements that we believe are appropriate to apply to cost contracts. In the case of contracts authorized under section 1876 of the Act, because section 1876 of the Act contains similar statutory language to that in Part C for

MA contracts, this language provides clear authority to impose the same policies to both types of contracts. We have expressly done this in past regulations. For example, given the similarities between the statutory language in sections 1876(c)(5) and 1852(g) of the Act, and the procedures for an independent review entity that existed in part 417 before Part C was enacted, we revised the part 417 beneficiary appeals regulations governing cost contract appeals authorized under section 1876 of the Act simply to incorporate the Part C beneficiary appeals regulations in part 422. MA contracts and cost contracts authorized under section 1876 of the Act similarly have had largely the same process concerning appeals of contract determinations, sanctions, and civil money penalties (CMPs). More recently, however, these processes have diverged, especially since the publication of final regulations revising the contract determination, sanctions, and CMP processes for MA organizations on December 5, 2007 (72 FR 68700 through 68741). Similarly, the marketing requirements for cost contracts, which at one time largely mirrored the MA requirements, have diverged. This is especially true since publication of our final regulations implementing significant changes to marketing standards, agent/broker compensation, and other marketing changes in 2008. As a result, there is sometimes confusion over which marketing requirements cost contract plans must follow.

Therefore, we are proposing in this rule, under the authority under section 1876(i)(3)(D) of the Act to impose "other terms and condition" under contracts authorized by the statute that the Secretary finds "necessary and appropriate," and in implementation of the provisions authorized by section 1876 of the Act set forth below, to apply the following MA program requirements to cost contracts authorized under section 1876 of the Act:

- Under the authority in section 1876(i)(1) of the Act to terminate or nonrenew contracts and the authority in section 1876(i)(6) of the Act to impose intermediate sanctions and CMPs, the MA program requirements on appeals processes for contract determinations and intermediate sanctions. (To the extent that the CMP in section 1876(i)(6)(B) and (C) of the Act differ from those under Part C, the penalty amounts under section 1876 of the Act would continue to control); and
- Under the authority in section 1876(c)(3)(C) of the Act to regulate marketing of plans authorized under

section 1876 of the Act and ensure that marketing material is not misleading, the MA program requirements for marketing to cost contract plans.

We discuss the above proposals for cost contracts authorized under section 1876 of the Act in greater detail in the sections that follow.

14. Appeals Processes for Contract Determinations, Intermediate Sanctions, and Civil Money Penalties

The policy reasons we gave in our December 2007 final rule for revising the contract determination and appeals processes for MA plans apply equally to cost contracts authorized under section 1876 of the Act. By extending the MA and Part D requirements regarding these processes to cost contracts authorized under section 1876 of the Act and organizations that have both MA and contracts authorized under section 1876 of the Act will also have a more efficient and clear path for appealing contract determinations, intermediate sanctions, and CMPs.

We are proposing to revise the following sections of the current contract requirements provisions of Part 417 authorized at section 1876 of the Act to specify that, with respect to appeals of contract determinations, intermediate sanctions and CMPs, cost contracts authorized under section 1876 of the Act would follow the provisions applicable to MA organizations at, respectively, Subpart N and Subpart T of part 422. With respect to appeals of intermediate sanctions, we are proposing to revise § 417.500 of the cost contracts requirements authorized under section 1876 of the Act to make these consistent, with the exception of some CMP amount provisions, with the sanctions processes for MA organizations. We discuss the proposed changes below.

a. Contract Determinations (§ 417.492 and 417.494)

Previous to the implementation of the contract determination requirements in the December 2007 final rule, the cost contracts authorized under section 1876 of the Act and MA plan contract determination requirements were very similar. Although we did not apply the provisions of the December 2007 regulations to cost contracts authorized under section 1876 of the Act at that time, we believe that it makes sense to do so now for the same reasons we made changes to the MA processes at that time.

As a result, we propose in § 417.492(b)(2), concerning notice of appeal rights, and § 417.494, concerning notice of termination, to require cost

contract plans to follow the contract determination appeal procedures under Subpart N of Part 422.

b. Civil Money Penalties (§ 417.500)

Currently, the regulations governing cost contracts authorized under section 1876 of the Act do not set forth a formal process for appealing CMPs. We propose these plans would follow the same requirements for CMP appeals that MA organizations follow. As a result, we propose to revise § 417.500 to require cost contracts authorized under section 1876 of the Act to follow the MA programs requirements for appeals of CMPs at Subpart T of Part 422. The appeals process for CMPs specified at Subpart T allows for a hearing by an Administrative Law Judge (ALJ) and a review of the ALJ's decision by the Departmental Appeals Board. In proposed new paragraph (c), we specify that the amount of CMPs a cost contract may be assessed is governed by section 1876(i)(6)(B) of the Act, not by the provisions in part 422 of the MA program regulations.

c. Intermediate Sanctions (§ 417.500)

Our proposed revision to the cost contracts regulations authorized under section 1876 of the Act would ensure that these contracts follow the same requirements for intermediate sanctions appeals specified in § 422.750 through § 422.764 of the MA program regulations (subpart O).

These sections concern—

- Types of intermediate sanctions and CMPs (§ 422.750);
 - Bases for intermediate sanctions and CMPs (§ 422.752);
 - Procedures for imposing intermediate sanctions and CMPs (§ 422.656);
 - Collection of CMPs (§ 422.758);
 - Settlement of penalties (§ 422.762);
- and
- Other applicable provisions (§ 422.764).

As noted above, with respect to determinations of the amount of CMPs, the provisions in section 1876(i)(6)(B) and (C) of the Act would govern such amounts.

15. Extending MA Marketing Requirements to Cost Program Plans (§ 417.428)

In 2008, we published several marketing-related regulations that significantly revised the marketing requirements for MA organizations and Part D sponsors. In the Medicare Advantage and Prescription Drug Benefit Programs; Final Marketing Provisions final rule, published in the September 18, 2008 **Federal Register** (73

FR 54208 through 54223), we discussed exclusively the marketing and established marketing standards including prohibiting soliciting door-to-door or through other unsolicited means for Medicare beneficiaries. A second regulation, the Revisions to the Medicare Advantage and Prescription Drug Benefit Programs IFC, also published in the September 18, 2008 **Federal Register** (73 FR 54226 through 54254), added requirements limiting agent and broker commissions. A third regulation, the Revisions to the Medicare Advantage and Prescription Drug Benefit Programs; Clarification of Compensation Plans IFC, published in the November 14, 2008 **Federal Register** (73 FR 67406 through 67414), clarified and augmented the agent broker requirements as specified. The new marketing regulations resulted in the creation of a new subpart V in parts 422 and 423. Although many of these provisions reflect or implement statutory provisions applicable only to MA plans and Part D plans, many of these same provisions were initially proposed under our broad authority to regulate marketing and impose new contract terms. As noted above, under this latter authority, we propose to amend § 417.428, which governs 1876 cost contract program marketing requirements, to require cost contract plans to follow the MA marketing requirements in § 422.2260 *et seq.* (Subpart V). We discuss the proposed marketing changes in the sections below.

a. Definitions Concerning Marketing Materials (§ 422.2260)

We are proposing that cost contracts authorized under section 1876 of the Act follow the same standards as MAOs under § 422.2260. Thus, cost contract plan marketing materials would include any materials which—

- Promote the cost contract, or any cost contract plan offered by the cost contract;
- Inform Medicare beneficiaries that they may enroll, or remain enrolled in, a cost contract plan offered by the cost contract;
- Explain the benefits of enrollment in a cost contract plan, or rules that apply to enrollees; and
- Explain how Medicare services are covered under a cost contract plan, including conditions that apply to such coverage.

b. Review and Distribution of Marketing Materials (§ 422.2262)

We propose that cost contracts authorized under section 1876 of the Act plan program marketing materials

be subject to the same marketing review guidelines and timelines as MA plans at § 422.2262. While section 1876(c)(3)(C) of the Act, like section 1851(h) of the Act, provides that marketing materials must be provided to CMS for review prior to use, and generally provides that such materials may be used after 45 days if we do not disapprove them, section 1876(c)(3)(C) of the Act does not include the shorter, 10-day timeframe that applies under section 1851(h)(5) of the Act in the case of marketing materials using model language. However, we believe that as long as material is submitted to CMS prior to use, we can authorize use by an earlier timeframe than that provided for under the applicable statute, or for use under conditions established by CMS for “deemed” approval under the file and use policy or as discussed in section II.G.15.d. of this proposed rule. Therefore, notwithstanding the differences in statutory language between sections 1876(c)(3)(C) and 1851(h) of the Act, we propose that the part 417 marketing regulations be revised to provide that cost contracts plans authorized under section 1876 of the Act submit all such marketing materials to CMS at least 45 days before the date planned for distribution (10 days if plans use CMS model language, without any modifications), and that file and use materials, as designated by CMS under the MA marketing regulations, may be released 5 days following their submission to CMS.

c. Guidelines for CMS Review (§ 422.2264)

In our proposal to apply the same standards to cost contract plans as currently applied to MAOs at § 422.2264, cost contractors authorized under section 1876 of the Act would be required to comply with MA regulations that specify the information that cost contract plans must include in marketing materials, and specify that the cost contract plan must notify the general public concerning the plan’s enrollment period. Under section 1876(i)(3)(D) of the Act, we also propose that in markets with a significant non-English speaking population, cost contract plans be required to provide materials in the language of these individuals.

d. Deemed Approval (§ 422.2266)

We propose to specify that if we have not disapproved the distribution of marketing materials or forms submitted by a cost contract plan in an area, we are deemed not to have disapproved the distribution in all other areas covered by the cost contract plan and cost contract

except with regard to any portion of the material or form that is specific to the particular area, as provided under § 422.2266.

e. Standards for MA Organization Marketing (§ 422.2268)

MA marketing standards we propose to extend to cost contract plans include the following provisions at § 422.2268:

- Plans may not offer gifts to potential enrollees, unless the gifts are of nominal (as defined in the CMS Marketing Guidelines) value, are offered to all potential employees without regard to whether or not the beneficiary enrolls, and are not in the form of cash or other monetary rebates.
- Plans may not market any health care-related product during a marketing appointment beyond the scope agreed upon by the beneficiary, and documented by the plan, prior to the appointment.
- Plans may not market additional health-related lines of plan business not identified prior to an in-home appointment without a separate appointment that may not be scheduled until 48 hours after the initial appointment.
- Plans may not use a plan name that does not include the plan type. The plan type should be included at the end of the plan name.

f. Licensing of Marketing Representatives and Confirmation of Marketing Resources (§ 422.2272)

As is the case currently for MAOs, we propose that cost contract plans authorized under section 1876 of the Act, consistent with § 422.2272:

- Demonstrate to CMS’ satisfaction that marketing resources are allocated to marketing to the disabled Medicare population as well as beneficiaries age 65 and over.
- Establish and maintain a system for confirming that enrolled beneficiaries have, in fact, enrolled in the plan, and understand the rules applicable under the plan.
- Employ as marketing representatives only individuals who are licensed by the State to conduct marketing activities (as defined in the Medicare Marketing Guidelines) in that State, and whom the cost program has informed that State it has appointed, consistent with the appointment process provided for under State law.

g. Broker and Agent Requirements (§ 422.2274)

Under section 1876(i)(3)(D) of the Act, we propose applying the MA limits on independent agent and broker compensation at § 422.2274 to 1876 cost

contract plans. As with MA plans, compensation would be based on a 6-year compensation cycle. Agents and brokers would receive initial compensation (first year of the cycle) with compensation over each of the successive 5 years to be no more and no less than 50 percent of the initial

aggregate compensation paid for the enrollment. If an enrollee moves to plan type distinct from the one in which he or she is currently enrolled, the agent/broker would receive an initial commission and the cycle would begin anew. Distinct plan types include MA, MA-PD, PDP, and cost contract plans

authorized under section 1876 of the Act.

H. Changes To Implement Corrections and Other Technical Changes

We propose six technical changes in this section outlined below.

TABLE 8—CHANGES TO IMPLEMENT CORRECTIONS AND OTHER TECHNICAL CHANGES

Provision	Part 422		Part 423	
	Subpart	Section	Subpart	Section
Applications of Subpart M to Health Care Prepayment Plans.	Subpart M ..	§ 417.840	N/A	N/A.
Generic Notice Requirements	Subpart M ..	§ 422.622, § 422.626	N/A	N/A.
Revision to Definition of Gross Covered Prescription Drug Costs.	N/A	N/A	Subpart G ..	§ 423.308.
Application Evaluation Procedures	Subpart K ..	§ 422.502(c) through (d)	Subpart K ..	§ 423.503(c) through (d).
Intermediate Sanctions	Subpart O ..	§ 422.750(a)	Subpart O ..	§ 423.750(a).
Basis for Imposing Intermediate Sanctions and Civil Money Penalties.	Subpart O ..	§ 422.752	Subpart O ..	§ 423.752.

1. Application of Subpart M to Health Care Prepayment Plans (§ 417.840)

As part of the January 28, 2005 Medicare Advantage (MA) final rule, we required cost plans (HMOs), including HCPPs, established under section 1876 of the Act (Part E) and regulated under Part 417, to follow the MA appeals requirements in Subpart M of Part 422. While the MA beneficiary appeals provisions in section 1852(g) of the Act and cost-HMO-CMP beneficiary appeals provisions in section 1876(c)(5) of the Act do not apply to HCPP enrollees, HCPP enrollees retain the general right to appeal Medicare coverage decisions consistent with section 1869 of the Act. In applying the MA appeals procedures to HCPPs by regulation, we adapted and implemented section 1869 appeal rights in the HCPP context. The regulations implementing section 1869 for services received on a fee-for-service basis through original Medicare do not address the case of services furnished by an HCPP in the managed care context.

Because HCPPs only provide Part B services, in our January 28, 2005 final rule (70 FR 4194), we limit the applicability of Subpart M to HCPP enrollees to only those provisions affecting Part B services. However, in doing so we inadvertently failed to include fast-track appeal rights regarding services provided by a (Part B) comprehensive outpatient rehabilitation facility (CORF). The proposed revision corrects this oversight, and ensures that HCPP enrollees have access to fast-track appeals for CORF services furnished by an HCPP. This would also effectuate for HCPP enrollees the fast track appeal

rights provided for under section 1869 of the Act.

2. Generic Notice Delivery Requirements (§ 422.622 and § 422.626)

We propose making two technical revisions in § 422.622 and § 422.626 to ensure that the MA regulations accurately state when plans and providers are responsible for delivering certain notices to enrollees. Section 422.622, states that when a QIO determines that an enrollee may remain in an inpatient setting, the MA organization must again provide the enrollee with a copy of the Important Message from Medicare (IM) when the enrollee no longer requires inpatient hospital care. However, the IM form instructions make clear that the IM is always delivered by a hospital. Similarly, in § 422.626, the current regulations make delivery of the Notice of Medicare Noncoverage (NOMNC) the MA organization's responsibility. Again, the form instructions for the NOMNC clearly state that the notice is to be delivered by the provider. Accordingly, we propose replacing "MA organization" with "hospital" in § 422.622, and "provider" in § 422.626.

3. Revision to Definition of Gross Covered Prescription Drug Costs (§ 423.308)

On January 12, 2009, we published a final rule (74 FR 1494) that included revisions to the definition of "gross covered prescription drug costs" in the Part D regulations at § 423.308. In amending § 423.308, we made a technical error in the definition of "gross covered prescription drug costs" (74 FR 1545) by referencing "negotiated

prices", the prices made available to Part D beneficiaries at network pharmacies, and not also referencing "usual and customary prices", the prices for drugs purchased at out-of-network pharmacies. When we revised the definition of "gross covered prescription drug costs" our intent was to clarify that Part D sponsors must use the amount received by the dispensing pharmacy or other dispensing provider as the basis for determining the drug costs that must be reported to us. The use of the term "negotiated prices" as defined at § 423.100 (74 FR 1544) in the definition of "gross covered prescription drug costs" clarifies this requirement with regards to covered Part D drugs purchased at network pharmacies. However, by not also referencing "usual and customary prices" for covered Part D drugs purchased at out-of-network pharmacies, we inadvertently omitted from the definition of "gross covered prescription drug costs" the share of drug costs actually paid by Part D sponsors to out-of-network pharmacies.

Section 1860D-15(b)(3) of the Act defines "gross covered prescription drug costs" as "the costs incurred under the [Part D] plan, not including administrative costs, but including costs directly related to the dispensing of covered part D drugs * * *." These costs include costs incurred for covered Part D drugs at out-of-network pharmacies, as well as costs incurred at network pharmacies. Therefore, we are proposing to revise the definition of "gross covered prescription drug costs" to correctly reference both "negotiated prices" paid to network pharmacies and "usual and customary prices" paid to out-of-network pharmacies. Specifically,

we are proposing to replace the term “negotiated price” with the term “actual cost,” which is defined at § 423.100 as “the negotiated price for a covered Part D drug when the drug is purchased at a network pharmacy, and the usual and customary price when a beneficiary purchases the drug at an out-of-network pharmacy consistent with § 423.124(a).” Thus, with this correction, the definition of gross covered prescription drug costs would include “the share of actual costs (as defined by § 423.100 of this part) actually paid by the Part D plan that is received as reimbursement by the pharmacy or other dispensing entity* * *.”

4. Application Evaluation Procedures (§ 422.502(c) and (d) and § 423.503(c) and (d))

Section 1857(a) of the Act provides the Secretary with the authority to enter into contracts with MA organizations, and section 1860D–12(b) (1) of the Act provides the Secretary with the authority to enter into contracts with PDP sponsors. Sections 422.502 and 423.503 provide the evaluation and determination procedures for approving or denying a contract application. We are proposing two amendments to these regulations in § 422.502(c) and (d), and § 423.503(c) and (d).

Currently, § 422.502(c)(3)(iii) and § 423.503(c)(3)(iii) state that if we deny the application, it gives written notice to the contract applicant indicating the applicant’s right to request reconsideration. In the December 5, 2007 final rule, we modified the appeal rights for initial applications and eliminated the reconsideration process. However, in the final regulations we did not update § 422.502(c)(3)(iii) and § 423.503(c)(3)(iii) to state that the applicant has a right to request a hearing and as a result the existing regulations incorrectly provide for a right to reconsideration. Therefore, at § 422.502(c)(3)(iii) and § 423.503(c)(3)(iii) we are proposing to make a technical correction and delete the language “right to reconsideration” and replace it with “right to request a hearing”.

Sections 422.502(d) and 423.503(d) currently provide that we have the ability to oversee the sponsoring organization’s continued compliance with the requirements and that if the sponsoring organization no longer meets those requirements, we will terminate the contract in accordance with § 422.510 and § 423.509. This regulation is not an appropriate regulation for a section dedicated to the evaluation and determination procedures for approving or denying a contract application.

Therefore, we are proposing to delete § 422.502(d) and § 423.503(d). The deletion of this language should not in any way be interpreted as limiting our ability to oversee a sponsoring organization’s compliance with our requirements as outlined at § 422.504 and § 423.505 or our ability to terminate a contract when a sponsoring organization no longer meets requirements as outlined in § 422.510(a) and § 423.509(a).

5. Intermediate Sanctions (§ 422.750(a) and § 423.750(a))

Sections 1857(g) and 1860D–12 of the Act provide the Secretary the ability to impose intermediate sanctions on sponsoring organizations. Section 422.750 and § 423.750 provide the types of intermediate sanctions that we may impose. Those intermediate sanctions are suspension of enrollment, suspension of payment, and suspension of all marketing activities. We are proposing to make technical changes to each intermediate sanction regulation to more accurately reflect the statute.

We are first proposing to change § 422.750(a)(1) and § 423.750(a)(1), which currently state that we may impose an intermediate sanction that requires the suspension of enrollment of Medicare beneficiaries. This regulation, as currently written, does not adequately reflect the statutory language which specifies that the enrollment suspension applies to the sponsoring organization’s enrollment of Medicare beneficiaries. Therefore, we are proposing to amend § 422.750(a)(1) and § 423.750(a)(1) to add language which makes it explicit that the suspension of enrollment applies to suspension of the sponsoring organization’s enrollment of Medicare beneficiaries.

We also are proposing to change the language of § 422.750(a)(2) and § 423.750(a)(2), which currently states that we may impose a suspension of payment to the sponsoring organization for Medicare beneficiaries who are enrolled in the MA plan. This language does not conform to the statutory language at section 1857(g)(2)(C) of the Act which states suspension of payment may be imposed for individuals enrolled after the date the Secretary notifies the organization of the imposition of an intermediate sanction. Therefore, we are amending § 422.750(a)(2) and § 423.750(a)(2) to add language that specifically states a suspension of payment applies to Medicare beneficiaries enrolled after the date we notify the organization of the intermediate sanction.

We are also proposing changes to § 422.750(a)(3) and § 423.750(a)(3),

which currently states that we may impose an intermediate sanction that requires the suspension of all marketing activities to Medicare beneficiaries by a sponsoring organization for specified MA or Part D “plans.” The use of the words “for specified” MA or Part D “plans” does not conform to the statutory language that applies intermediate sanctions at the organization level. Therefore, we are amending § 422.750(a)(3) and § 423.750(a)(3) to conform to the statutory language by deleting the words “for specified MA or Part D plans.”

6. Basis for Imposing Intermediate Sanctions and Civil Money Penalties (§ 422.752 and § 423.752)

Sections 1857(g) and 1860D–12 of the Act provide a list of bases for intermediate sanctions and civil money penalties. Existing regulations at § 422.752(a) and § 423.752(a) provide a similar list of bases for intermediate sanctions and civil money penalties. However, the language provided in § 422.752(a)(1), (3), and (4) and § 423.752(a)(1), (3), and (4) does not adequately conform to the statutory language in section 1857(g)(1)(A), (C), and (D) of the Act, respectively. Specifically, section 1857(g)(1) of the Act states the Secretary may impose an intermediate sanction if it determines that the sponsoring organization: (A) Fails substantially to provide medically necessary items and services that are required (under law or under the contract) to be provided to an individual covered under the contract, if the failure has adversely affected (or has substantial likelihood of adversely affecting) the individual; (C) acts to expel or to refuse to re-enroll an individual in violation of the provisions of this part; and (D) engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by this part) by eligible individuals with the organization whose medical condition or history indicates a need for substantial future medical services. To ensure accuracy, consistency and uniformity we are making conforming changes to our regulation at § 422.752(a)(1), (3), and (4) and § 423.752(a)(1), (3), and (4) to more accurately reflect the statutory language.

First, § 422.752(a)(1) states that we may impose an intermediate sanction if the sponsoring organization fails substantially to provide, to a sponsoring organization enrollee, medically necessary services that the organization is required to provide (under law or under the contract) to a sponsoring organization enrollee, and that failure

adversely affects (or is substantially likely to adversely affect) the enrollee. This language is slightly different than the language provided in the statute at section 1857(g)(1)(A) of the Act. Therefore, we are proposing to amend § 422.752(a)(1) and § 423.752(a)(1) to conform with the statutory language and state that we may impose an intermediate sanction if the sponsoring organization fails substantially to provide medically necessary items and services that are required (under law or under the contract) to be provided to an individual covered under the contract, if the failure has adversely affected (or has substantial likelihood of adversely affecting) the individual.

Second, § 422.752(a)(3) and § 423.752(a)(3) states that we may impose an intermediate sanction if the sponsoring organization expels or refuses to reenroll a beneficiary in violation of the provisions of this part. This language does not include the word "acts" to expel which is mentioned in the statute at section 1857(g)(1)(C) of the Act. Therefore, we are proposing to amend § 422.752(a)(3) and § 423.752(a)(3) to conform with the statutory language and state that we may impose an intermediate sanction if the sponsoring organization "acts" to expel or refuses to re-enroll a beneficiary in violation of the provisions of this part.

Third, § 422.752(a)(4) and § 423.752(a)(4) states that we may impose an intermediate sanction if the sponsoring organization engages in any practice that could reasonably be expected to have the effect of denying or discouraging enrollment of individuals whose medical condition or history indicates a need for substantial future medical services. This language does not match the exact language contained in section 1857(g)(1)(D) of the Act. Therefore, we are proposing to amend § 422.752(a)(4) and § 423.752(a)(4) to conform with the statutory language and state that we may impose an intermediate sanction if the sponsoring organization engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by this part) by eligible individuals with the organization whose medical condition or history indicates a need for substantial future medical services.

We are also proposing to make conforming changes to § 422.752(c) and § 423.752(c). Currently § 422.752(c)(1) and § 423.752(c)(1) state that we may impose civil money penalties for any of the determinations at § 422.510(a) and § 423.509(a), except § 422.510(a)(4) and § 423.509(a)(4). Also, § 422.752(c)(2)(ii)

and § 423.752(c)(2)(ii) state that OIG may impose civil money penalties for a determination made pursuant to § 422.510(a)(4) and § 423.509(a)(4). Since we are proposing elsewhere in these proposed regulations to redesignate § 422.510(a)(4) and § 423.509(a)(4) to § 422.510(a)(2)(iii) and § 423.509(a)(2)(iii), we need to conform § 422.752 and § 423.752 to these changes. Therefore, for regulations § 422.752(c)(1), § 422.752(c)(2)(ii), § 423.752(c)(1), and § 423.752(c)(2)(ii) we are proposing to delete the reference to § 422.510(a)(4) and § 423.509(a)(4) and replace them with a reference to § 422.510(a)(2)(iii) and § 423.509(a)(2)(iii).

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. ICRs Regarding Basic Contract Requirements (§ 417.472)

Proposed § 417.472(i) states that HMO or CMP must comply with the requirements at § 422.152(b)(5). Proposed § 417.472 states that all coordinated care contracts (including local and regional PPOs and contracts with exclusively SNP benefit packages, cost contracts under section 1876 of the Act, private fee-for-service contracts, and MSA contracts with 600 or more enrollees in July of the prior year) must contract with approved Medicare Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey vendors to conduct the Medicare CAHPS satisfaction survey of MA plan

enrollees in accordance with CMS specifications and submit the survey data to CMS. The burden associated with the requirement in § 417.472(i) and (j) is detailed in our discussion of § 422.152(b)(5).

B. ICRs Regarding Apportionment and Allocation of Administrative and General Costs (§ 417.564)

We are not imposing any new reporting requirements. We are simply clarifying what costs an HCPP may report in its cost report as administrative costs for reimbursement from the government. We do not believe that our proposal will result in additional burden on cost plans; therefore, we have not incorporated a burden increase in the PRA section. However, we solicit comment on our burden estimates.

C. ICRs Regarding Medicare Secondary Payer (MSP) Procedure (§ 422.108 and § 423.462)

Section 422.108(b)(3) proposes that MA organizations must coordinate benefits to Medicare enrollees with the benefits of the primary payers, including reporting, on an ongoing basis, information obtained in accordance with requirements in paragraphs (b)(1) and (b)(2) of this section in accordance with CMS instructions. Similarly, § 423.462 proposed that Part D plan sponsors must report creditable new or changed primary payer information to the CMS Coordination of Benefits Contractor in accordance with the processes and timeframes specified by CMS. The burden associated with this requirement is the time and effort necessary to report the specified information to CMS on an ongoing basis. We estimate that 624 MA organizations and 456 Part D plan sponsors must comply with these requirements, a total of 1,080 entities. We also estimate that, on average, each entity will produce one report thereby yielding a total of 1,080 reports annually for involved entities. It will take each entity an average of 2,885 hours to report the required information to CMS. The estimated annual burden associated with these requirements is 3,115,800 hours. The cost associated with meeting these requirements is \$77.9 million.

D. ICRs Regarding Disclosure Requirements (§ 422.111)

Proposed § 422.111 states that we may require an MA organization to self-disclose to its enrollees or potential enrollees, the MA organization's performance and contract compliance deficiencies in a manner specified by CMS. The burden associated with this

requirement is the time and effort necessary for an MA organization to make the aforementioned disclosures. We have not accounted for the burden associated with this provision for two reasons. First, we may require organizations that are under enforcement actions to disclose their compliance deficiencies in a letter to their existing members. However, the number of organizations that receive enforcement actions per year does not exceed the PRA threshold of 10. Based on past history and experience, we have not imposed intermediate sanctions on more than 10 plans in a given year. For example, there have been a total of 4 organizations with intermediate sanctions imposed this year which is the highest number of intermediate sanctions imposed during the past 4 years. Second, for organizations that are not under enforcement action, we may require them to disclose compliance and performance deficiencies but only in their existing marketing or enrollment materials sent to current and potential enrollees. There will be no requirement for them to submit additional materials to enrollees. We solicit comment on whether these provisions could impact 10 or more plans and whether these burdens should be accounted for under the PRA.

E. ICRs Regarding Quality Improvement Program (§ 422.152)

Proposed § 422.152(b)(3)(ii) states that MA coordinated care plans must collect, analyze and report quality performance data identified by CMS that are of the same type as those specified under paragraph (b)(3)(i) of this section. The burden associated with these requirements is the time and effort necessary for an MA coordinated care plan to collect, analyze and report quality performance data to CMS. We estimate that it will require 1,000 hours per MA coordinated care plan to comply with these requirements. There are 624 MA coordinated care plans. The estimated annual burden associated with these requirements is 624,000 hours. The estimated annual cost associated with these requirements is \$36.9 million.

Proposed § 422.152(b)(5) requires that all coordinated care contracts (including local and regional PPOs and contracts with exclusively SNP benefit packages, cost contracts under section 1876 of the Act, private fee-for-service contracts, and MSA contracts with 600 or more enrollees in July of the prior year) must contract with approved Medicare Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey vendors to conduct the Medicare

CAHPS satisfaction survey of MA plan enrollees in accordance with CMS specifications, and submit the survey data to CMS. The burden associated with this requirement is the time and effort necessary to conduct the CAHPS survey and submit the corresponding data to CMS. While this requirement is subject to the PRA, the associated burden is currently approved under OMB control number 0938-0732.

Proposed § 422.152(e)(2)(ii) states that MA organizations offering an MA regional plan or local PPO plan must collect, analyze and report quality performance data identified by CMS that are of the same type as those described under § 422.152(e)(2)(i). The burden associated with these requirements is the time and effort necessary for an MA organization offering an MA regional plan or local PPO plan to collect, analyze and report quality performance data to CMS. We estimate that it will require 54 hours per MA organization to comply with these requirements; there are 509 organizations offering an MA regional plan or local PPO. The estimated annual burden associated with these requirements is 27,486 hours. The estimated annual cost associated with these requirements is \$3.1 million.

F. ICRs Regarding RADV Audit Dispute and Appeal Processes (§ 422.311)

Proposed § 422.311(c)(1) discusses the attestation process with regard to the RADV audit dispute and appeal processes. Specifically, proposed § 422.311(c)(1)(i)(A) states that subsequent to the conduct of a RADV audit, MA organizations may submit CMS-generated attestations from physician/practitioner(s) in order to dispute signature or credential related RADV errors. Proposed § 422.311(c)(1)(iv)(A) states that CMS notifies an MA organization of their RADV audit status, we will provide the attestation forms and submission instructions. As stated in proposed § 422.311(c)(1)(iv)(B), MA organizations are required to submit the attestation to CMS at the same time that the MA organization is required to submit related medical records for RADV audits.

The burden associated with the requirements in this section is the time and effort necessary for MA organizations to complete the CMS-generated attestations and to submit the related documentation to CMS. While these requirements are subject to the PRA, we believe the associated burden is exempt from the PRA under 5 CFR 1320.3(h)(1). As stated in 5 CFR 1320.3(h)(1), information does not

generally include items in the following categories, which include but are not limited to affidavits, oaths, affirmations and certifications, provided that they entail no burden other than that necessary to identify the respondent, the date, the respondent's address, and the nature of the instrument. Similarly, we believe the burden associated with the aforementioned information collection requirements is exempt from the PRA under 5 CFR 1320.4. Information collected during the conduct of an administrative action or audit is not subject to the PRA.

Proposed § 422.311(c)(2) states that an MA organization may choose to dispute CMS' operational processing of RADV medical records using a CMS-administered documentation dispute process.

Proposed § 422.311(c)(2)(iii)(B) states that MA organizations have 30 days from the date of issuance of the RADV audit report to request a documentation dispute. Proposed § 422.311(c)(2)(iv) outlines the documentation dispute review and notification procedures. The burden associated with the requirements in this section is the time and effort necessary for an MA organization to request a documentation dispute. While this requirement is subject to the PRA, we believe the associated burden is exempt under 5 CFR 1320.4. Information collected during the conduct of an administrative action or audit is not subject to the PRA.

Proposed § 422.311(c)(3) describes the RADV payment error appeal process. Specifically, proposed § 422.311(c)(3)(iii) states that at the time CMS issues its RADV audit report, we notify affected MA organizations in writing of their appeal rights around the RADV payment error calculation. The MA organizations have 30 days from the date of this notice to submit a written request for reconsideration of its RADV payment error calculation. The burden associated with this requirement is the time and effort necessary for an MA organization to draft and submit a redetermination request that contains the content specified in proposed § 422.311(c)(3)(v). While this requirement is subject to the PRA, we believe the associated burden is exempt under 5 CFR 1320.4. Information collected during the conduct of an administrative action or audit is not subject to the PRA.

Proposed § 422.311(c)(4) states that an MA organization that is dissatisfied with the written decision of the CMS reconsideration official is entitled to a hearing as provided in this section. The organization's request for a hearing must be made in writing and filed with CMS

within 30 days of the date CMS and the MA organization receive CMS' written reconsideration decision. The reconsideration request must contain the information listed in proposed § 422.311(c)(4)(ii). The burden associated with this requirement is the time and effort necessary for an MA organization to draft and submit a hearing request. While this requirement is subject to the PRA, we believe the associated burden is exempt under 5 CFR 1320.4. Information collected during the conduct of an administrative action or audit is not subject to the PRA.

G. ICRs Regarding Application Requirements (§ 422.501 and § 423.502)

Proposed § 422.501(b) and proposed § 423.502(b) require that an organization submitting an application under this section for a particular contract year must first submit a completed Notice of Intent to Apply by the date established by CMS. We will not accept applications from organizations that do not submit a timely Notice of Intent to Apply. The purpose of these requirements is to facilitate CMS systems access earlier so that the contract number may be given out and applications may be submitted electronically. While the burden associated with the requirements contained in proposed § 422.501(b) and proposed § 423.502(b), the Notice of Intent to Apply, is subject to the PRA, the burden associated with these requirements is already approved under the OMB control numbers for the Part C and Part D applications, 0938–0935 and 0938–0936, respectively.

Section 422.501(c) and § 423.502(c) propose to revise the current regulation, making clear the application standards for becoming an MA organization or Part D plan sponsor. Specifically, proposed § 422.501(c) and § 423.502(c) would require that applicants complete all parts of a certified application. The burden associated with the aforementioned requirements is the time and effort necessary for an applicant to complete all parts of a certified Part C or Part D application. While the burden associated with the requirements contained in proposed § 422.501(c) and proposed § 423.502(c) is subject to the PRA, the burden associated with these requirements is already approved under OMB control numbers for the Part C and Part D applications, 0938–0935 and 0938–0936, respectively.

The costs associated with submitting the applications approved under 0938–0935 and 0938–0936 are \$864,600 and \$655,559, for MA plans and Part D plan sponsors, respectively.

H. ICRs Regarding General Provisions (§ 422.503 and § 423.504)

Section 422.503(b)(4)(vi) and § 423.504(b)(4)(vi) propose to expand on the existing requirements by providing clarification and additional guidance with respect to the requirements for developing, implementing and maintaining effective compliance programs. We believe the requirements contained in § 422.503(b)(4)(vi) and § 423.504(b)(4)(vi) will assist sponsoring organizations further improving their existing compliance programs. While these requirements are subject to the PRA, we believe the associated burden is part of usual and customary business practices and thereby exempt under 5 CFR 1320.3(b)(2). However, we solicit comment on our assessment and whether these burdens are, in fact, part of usual and customary business practices.

I. ICRs Regarding Contract Provisions (§ 422.504 and § 423.505)

Proposed § 422.504 and § 423.505 explicitly state our existing authority to find sponsors out of compliance with either MA requirements, Part D requirements, or both when the sponsor's performance represents an outlier relative to the performance of other sponsors. Specifically, proposed § 422.504(e)(2) and § 423.505(e)(2) state that HHS, the Comptroller General or their designees have the right to audit, evaluate, and inspect any books, contracts, computer or other electronic systems, including medical records and documentation of the first tier, downstream, and related to our contract with the MA organization. These proposed sections contain recordkeeping requirements. The burden associated with proposed § 422.504(e)(2) and § 423.505(e)(2) is the time and effort necessary for MA organizations or Part D sponsors to maintain the information on file and make it available to CMS upon request. While these requirements are subject to the PRA, we believe the associated burden is exempt under 5 CFR 1320.3(b)(2). However, we solicit comment on our assessment and whether these burdens are, in fact, part of usual and customary business practices.

J. ICRs Regarding Nonrenewal of Contract (§ 422.506 and § 423.507)

Proposed § 422.506 and § 423.507 contain notification requirements for MA organizations and Part D plan sponsors. Section 422.506(a)(2) and § 423.507(a)(2) propose to require that when an organization does not intend to

renew its contract, it must notify each Medicare enrollee by mail at least 90 calendar days before the date on which the nonrenewal is effective. An organization would also have to provide information about alternative enrollment options by complying with at least one of the requirements specified in proposed § 422.506(a)(2)(ii) or § 423.507(a)(2)(ii). In addition, proposed § 422.506(b)(2) and § 423.507(b)(2) state that an organization notify each Medicare enrollee by mail at least 90 calendar days before the date on which the nonrenewal is effective, or at the conclusion of the appeals process if applicable.

The burden associated with the aforementioned requirements is the time and effort necessary for an organization to notify its Medicare enrollees by mail at least 90 calendar days before the date on which the nonrenewal is effective, or at the conclusion of the appeals process if applicable. While this requirement is subject to the PRA, we are unable to accurately quantify the burden because we cannot estimate the number of organizations that may not renew their contracts from year to year. We believe that less than 10 contracts will be terminated on an annual basis; however, we welcome public comments on these information collection requirements and whether the PRA would apply. We will reevaluate this issue in the final rule stage of rulemaking.

K. ICRs Regarding Request for Hearing (§ 422.662 and § 423.651)

With respect to Medicare contract determinations and appeals, § 422.662 and § 423.651 propose the requirements for submission methods and time for filing requirements for MA organizations and Part D plan sponsors that want to request a hearing for a determination under appeal. The request for hearing must be submitted in writing and must be filed within 15 calendar days after the receipt of the notice of the contract determination or intermediate sanction. The PRA is not applicable to this proposal because there are no additional requirements for sponsoring organizations. This is an existing regulation and we are only modifying the language "after receipt of the hearing decision" to conform to other regulations.

L. ICRs Regarding Time and Place of Hearing (§ 422.670 and § 423.655)

Proposed § 422.670 and § 423.655 state that CMS, an MA organization or a Part D plan sponsor may request an extension by filing a written request no later than 5 calendar days prior to the scheduled hearing. The burden

associated with these requirements is the time and effort necessary for an MA organization or a Part D plan sponsor to submit a written extension request to the presiding hearing officer. While this requirement is subject to the PRA, we believe the associated burden is exempt from the PRA as stated under 5 CFR 1320.4. Information collected during the conduct of an administrative action is not subject to the PRA.

M. ICRs Regarding Review by the Administrator (§ 422.692 and § 423.666)

Proposed § 422.692 and § 423.666 state that CMS, an MA organization or a PDP plan sponsor that has received a hearing decision may request a review by the Administrator within 15 calendar days after receipt of the hearing decision. The burden associated with these requirements is the time and effort necessary to submit a request for the Administrator to review a hearing decision. The PRA is not applicable to this proposal because there are no additional requirements for sponsoring organizations. This is an existing regulation and we are only modifying the language “after receipt of the hearing decision” to conform to other regulations.

N. ICRs Regarding Procedures for Imposing Intermediate Sanctions and Civil Monetary Penalties (§ 422.756 and § 423.756)

Proposed § 422.756 and § 423.756 state before CMS imposes intermediate sanctions, MA organizations and Part D plan sponsors may request a hearing before a CMS hearing officer. A written request must be received by the designated CMS office within 15 calendar days of the receipt of the notice of sanction. The burden associated with these requirements is the time and effort necessary to draft and submit a hearing request to the designated CMS office. The PRA is not applicable to this proposal because there are no additional requirements for sponsoring organizations. This is an existing regulation and we are only modifying the language “after receipt of the hearing decision” to conform to other regulations.

O. ICRs Regarding Disclosure of Part D Plan Information (§ 423.128)

Proposed § 423.128 states that we may require a Part D plan sponsor to self-disclose to its enrollees or potential enrollees, the Part D plan sponsor's performance and contract compliance deficiencies in a manner specified by CMS. We believe the burden associated with this requirement is the time and effort necessary for a Part D plan

sponsor to disclose the aforementioned information. We do not believe the PRA is applicable for this proposal for two reasons.

First, we may require organizations that are under enforcement actions to disclose their compliance deficiencies in a letter to their existing members. Based on past history and experience, we have not imposed intermediate sanctions on more than 10 plans in a given year. For example, there have been a total of 4 organizations with intermediate sanctions imposed this year which is the highest number of intermediate sanctions imposed during the past 4 years. We believe the burden associated with the requirement is not subject to the PRA under 5 CFR 1320.3(c), which defines the agency collection of information subject to the requirements of the PRA as information collection imposed on 10 or more persons within any 12-month period. This information collection does not impact 10 or more entities in a 12-month period. However, we welcome public comments on this issue. We will reevaluate this issue in the final rule stage of rulemaking.

Second, for organizations that are not under enforcement action, we may require them to disclose compliance and performance deficiencies but only in their existing marketing or enrollment materials sent to current and potential enrollees.

While we do not believe this additional disclosure would increase burden or costs to organizations, we solicit comment on our burden estimates and assumptions.

P. ICRs Regarding Consumer Satisfaction Surveys (§ 423.156)

Proposed § 423.156 requires Part D contracts with 600 or more enrollees as of July of the prior year to contract with approved Medicare Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey vendors to conduct the Medicare CAHPS satisfaction survey of Part D plan enroll enrollees in accordance with CMS specifications and submit the survey data to CMS. The burden associated with this requirement is the time and effort necessary to conduct the CAHPS survey and submit the corresponding data to CMS. While this requirement is subject to the PRA, the associated burden is currently approved under OMB control number 0938–0732.

Q. ICRs Regarding Validation of Part C and Part D Reporting Requirements (§ 422.516 and § 423.514)

We propose to amend § 422.516 and § 423.514 to state that each Part C and

Part D sponsor be subject to an independent yearly audit of Part C and Part D measures (collected pursuant to our reporting requirements) to determine their reliability, validity, completeness, and comparability in accordance with specifications developed by CMS. The burden associated with this proposed provision is the time and effort of the MA organizations and Part D sponsors in procuring an auditor and in supporting the auditor as well as the time and effort of the auditor in conducting the yearly audit. We estimate that the total yearly hourly burden for procuring and supporting the auditor is equal to the number of sponsors (710) × the average estimated hours per sponsor (120). This equals 85,200 hours. We estimated that the average number of hours for the auditor to conduct an audit was 304. The total estimated hours to conduct audits across all sponsors would then be $710 \times 304 = 215,840$. The total hours would be $85,200 + 215,840 = 301,040$. The estimated annual cost associated with these requirements is \$45.6 million.

R. ICRs Regarding Drug Utilization Management, Quality Assurance, and Medication Therapy Management Programs (MTMPs) (§ 423.153)

The proposed revisions to § 423.153 state that Part D plans must offer a minimum level of medication therapy management services for each beneficiary enrolled in the MTMP that includes but is not limited to annual comprehensive medication reviews with written summaries. The comprehensive medical review must include an interactive, person-to-person consultation performed by a pharmacist or other qualified provider unless the beneficiary is in a long-term care setting. Additionally, there must be quarterly targeted medication reviews with follow-up interventions when necessary.

The burden associated with these requirements is the time and effort necessary for a Part D sponsors (both MA-PDs and PDPs) to conduct the medical reviews with written summaries. We estimate that each medical review will take an average of 30 minutes to conduct. Similarly, we estimate that there will be 1,875,000 reviews conducted by 456 Part D sponsors on an annual basis. The total annual burden associated with this requirement is 937,500 hours.

S. ICRs Regarding Timeframes and Notice Requirements for Standard Coverage Determinations (§ 423.568)

If a Part D plan sponsor makes a completely favorable standard decision under paragraph (b) of this section, it must give the enrollee written notice of the determination. The initial notice may be provided orally, so long as a written follow-up notice is sent within 3 calendar days of the oral notification.

The burden associated with the requirement proposed in paragraph (d) is the time and effort necessary for a Part D plan sponsor to notify an enrollee (and the prescribing physician or other prescriber involved, as appropriate) in writing of completely favorable standard decision for benefits. We estimate that each year, the 456 Part D plan sponsors will issue a total of approximately 760,411 written favorable standard notifications for benefits. We further estimate that it will take a Part D plan sponsor 30 minutes to distribute a single notice. The estimated annual burden associated with the requirement in proposed § 423.568(d) is 380,206 hours. The estimated annual cost associated with these requirements is \$15.2 million.

T. ICRs Regarding Timeframes and Notice Requirements for Expedited Coverage Determinations (§ 423.572)

If a Part D plan sponsor makes a completely favorable expedited decision under paragraph (b) of this section, it must give the enrollee written notice of the determination. The initial notice may be provided orally, so long as a written follow-up notice is sent within 3 calendar days of the oral notification. The burden associated with the requirements listed in § 423.572(b) is the time and effort necessary for a Part D plan sponsor to notify an enrollee (and the prescribing physician or other prescriber involved, as appropriate) in writing of completely favorable expedited decision. We estimate that

each of the 456 Part D plan sponsors will issue an average of 87,103 written favorable expedited notifications per year. We further estimate that it will take a Part D plan sponsor 30 minutes to distribute a single notice. The estimated annual burden associated with the requirement in § 423.572(b) is 43,552 hours. The estimated annual cost associated with these requirements is \$15.2 million.

U. ICRs Regarding Access to Covered Part D Drugs (§ 423.120)

Proposed § 423.120(b)(iv) would require sponsors to provide enrollees with appropriate notice regarding their transition process within a reasonable amount of time after providing a temporary supply of non-formulary Part D drugs (including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a sponsor's utilization management rules). The burden associated with this requirement is the time and effort necessary for a Part D plan sponsor to provide a notice to beneficiaries regarding the transition process. We estimate this would result in 1.35 million notices that would take an average of 15 minutes to prepare. We then estimate the total burden to be 337,500 hours.

Proposed § 423.120(c)(3) would require Part D sponsors to contractually mandate that their network pharmacies submit claims electronically to the Part D sponsor or its intermediary on behalf of the beneficiary whenever feasible unless the enrollee expressly requests that a particular claim not be submitted to the Part D sponsor or its intermediary. Proposed § 423.120(c)(3) would require the approximately 28 pharmacy claims processors currently responsible for the electronic adjudication of pharmacy benefits to change their RxBIN or RxBIN and RxPCN combination if such identifiers are not already unique to its Medicare

line of business, and the Part D cardholder identification number if it is not already unique to each Medicare Part D enrollee. We estimate the annual hourly burden to be 1,380 hours per processor to make the coding changes necessary to implement this requirement. There are an estimated 28 processors. At an estimated \$150 cost per hour for the fully loaded labor of a computer programmer, we estimate the yearly burden to be 38,640 hours for CY 2010. This is a one-time only burden for programming.

The estimated annual cost associated with requirements associated with the transition process is \$6.8 million.

V. ICRs Regarding Timeframes and Responsibility for Making Redeterminations (§ 423.590)

Proposed § 423.590(d)(2) states that if a Part D plan sponsor first notifies an enrollee of an adverse or favorable expedited determination orally, it must mail written confirmation to the enrollee within 3 calendar days of the oral notification. The burden associated with this requirement is the time and effort necessary for a Part D plan sponsor to follow up an initial oral notification to an enrollee with a written notification. We estimate that each of the 456 Part D plan sponsors will have to distribute approximately 95 notices for an estimated annual number of 43,320 responses. Similarly, we estimate that the work will be conducted at a rate of \$40 per hour. The estimated annual cost associated with this requirement is \$1.733 million.

W. Annual Information Collection Burden

Table 9 shows our estimates of the annual reporting and recordkeeping burden based on the discussion detailed in sections III.A. through III.V. of this proposed rule.

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TABLE 9--Estimated Annual Reporting, Recordkeeping and Cost Burdens

Regulation Section(s)	OMB Control No.	Respondents	Responses	Burdens per Response (hours)	Total Annual Burden (hours)	Total Annual Cost Burden (\$ in millions)	Hourly Labor Cost of Reporting	Total Labor Cost of Reporting (\$ in millions)	Total Capital/Maintenance Costs (\$ millions)	Total Costs (\$ millions)
§422.108 and §423.462	0938-New	1,080	1,080	2,885	3,115,800	77.9	25	77.9	0	77.9
§422.152 (b)(3)(ii)	0938-New	624	624	1,000	624,000	36.9	59.13	36.9	0	36.9
§422.152(b)(5)	0938-0732	660,000	660,000	0.33	217,800	0	0	0	0	0
§422.152(c)(2)(ii)	0938-New	509	509	54	27,486	3.1	112.78	3.1	0	3.1
§422.501	0938-0935	291	291	32.8	9,547	0.9	90.56	0.9	0	0.9
§423.502	0938-0936	453	453	26.3	11,919	0.7	55.00	0.7	0	0.7
§423.156	0938-0732	660,000	660,000	0.33	217,800	0.0	0.00	0.0	0	0.0
§422.516 and §423.514	0938-New	710	710	425	301,840	45.6	151.07	45.6	0	45.6
§422.568 and §423.568	0938-New	1,080	21,232	0.5	10,616	0.4	40	0.4	0	0.4
§423.568	0938-New	456	760,411	0.5	380,206	15.2	40	15.2	0	15.2
§423.120(b)(iv)	0938-New	456	1,350,000	0.15	337,500	6.8	20.15	6.8	0	6.8
§423.120(c)(3)	0938-New	28	28	1380	38,640	0	0	0	5.8	5.8
§423.153	0938-New	456	1,875,000	0.5	937,500	112.5	120	112.5	0	112.5
§423.590	0938-New	456	43,550	1	43,550	1.7	40	1.7	0	1.7
§423.572	0938-0976	758	290,344	0.5	145,172	15.2	104.70	15.2	0	15.2
Total/Average					6,419,376	316.8	49.35	316.8	5.8	322.6

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. E-mail comments to the Office of Information and Regulatory Affairs, Office of Management and Budget to oir_submission@omb.eop.gov or fax comments to 202-395-7285. Please reference this rule (CMS-4085-P) and mark your comments to the attention of CMS desk officer.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Analysis

A. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year).

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number 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 \$34.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. MA organizations and Part D sponsors, the only entities that will be affected by the provisions of this rule, are not generally considered small business entities. They must follow minimum enrollment requirements (5,000 in urban areas and 1,500 in non-urban areas) and because of the revenue from such enrollments, these entities are generally above the revenue threshold required for analysis under the RFA. While a very small rural plan could fall below the threshold, we do not believe that there are more than a handful of such plans. A fraction of MA organizations and sponsors are considered small businesses because of their non-profit status. For an analysis to be necessary, however, 3 to 5 percent of their revenue would have to be affected by the provisions. We do not believe that this threshold would be reached by the proposed requirements. Therefore, the Secretary has determined that this proposed rule will not have a significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis, if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we believe and the Secretary has determined that this 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 by State, local or tribal governments, in the aggregate, or by the private sector of \$100 million in 1995 dollars, updated annually for inflation. That threshold level is currently \$133 million. This proposed rule is expected to reach this spending threshold.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule and subsequent final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications.

We do not believe that this proposed rule imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications.

Because there are costs to plans and sponsors associated with several provisions of this rule, we indicate general areas affected and specify the costs associated with these. For specific burden associated with the requirements and the bases for our estimates, see section III. of this proposed rule.

We estimate this rule is “economically significant” as measured by the \$100 million threshold, and hence a major rule under the Congressional Review Act. Accordingly, we have prepared a Regulatory Impact Analysis.

B. Increase in Costs to MA Organizations and Part D Sponsors

The provisions of this proposed rule would require MA organizations and Part D sponsors an estimated cost of approximately \$321.68 million for CY 2010. We believe the following requirements will result in monetized transfers from the Federal Government to MA organizations and Part D sponsors between 2011 and 2015. Risk Adjustment Validation (Part 422), Quality Improvement program (§ 422.152), Medicare Secondary Payer Procedures (§ 422.108), Validation of Reporting Requirements (§ 422.516 and § 423.514), the Quality Improvement Program and Consumer Satisfaction Surveys (§ 422.152 and § 423.156), Providing Written Notifications (§ 422.568(e)), Organization Determinations, Transition Process Notice (§ 423.120), Standard Timeframe and Notice Requirements for Coverage Determinations (§ 423.568), Drug Utilization Management, Quality Assurance, and Medication Therapy Management Programs (§ 423.153), and Pharmacy Use of Standard Technology under Part D (§ 423.120(c)(3)). We believe that the MIPPA 176 provision will result in savings. However, the MIPPA 176 provision will not take effect until CY 2011. Most of the proposed changes do not require additional data collection or reporting burden but rather involve clarification or codification of current policy. The economic impact will be funded through monetized transfers from the Federal government to health plans and through increases in beneficiary premiums. We expect that these expenses will be largely reflected in higher bid prices. Given that there are approximately 27 million PDP enrollees and an additional 8 million MA

enrollees, the impact on the premium per enrollee will be minimal. In CY 2010, the estimated cost is

approximately \$3.2 million, translating to under \$10.00 per enrollee. The affect on the monthly premium would be less

than \$1.00. The estimated impact on enrollees would appear to be negligible.

TABLE 10—ESTIMATED COSTS AND SAVINGS BY PROVISION FOR CYS 2010–2015

[\$ in millions]

	Calendar year						
	2010	2011	2012	2013	2014	2015	2010–2015
RADV	\$3.98	\$3.98	\$3.98	\$3.98	\$3.98	\$3.98	\$23.88
Quality	36.9	36.9	36.9	36.9	36.9	36.9	221.4
MSP	77.9	77.9	77.9	77.9	77.9	77.9	467.4
Validation of Reporting Requirements	45.6	45.6	45.6	45.6	45.6	45.6	273.6
CAHPS	0.0	3.1	3.1	3.1	3.1	3.1	15.5
Written Notifications	17.0	17.0	17.0	17.0	17.0	17.0	102.0
MIPPA 176	0.0	–90.0	–210.0	–300.0	–340.0	–380.0	–1,320.0
Organization Determinations	15.2	15.2	15.2	15.2	15.2	15.2	91.2
Transition Process	6.8	6.8	6.8	6.8	6.8	6.8	40.8
Drug Utilization Management	112.5	112.5	112.5	112.5	112.5	112.5	675.0
Pharmacy Use of Standard Technology	5.8	0.0	0.0	0.0	0.0	0.0	5.8
Total Cost/Savings	321.68	228.98	108.98	18.98	–21.02	–61.02	596.58

C. Expected Benefits

Beginning in CY 2014, we expect net savings due to the combined impact of these new proposed provisions. We expect that the net impact across the 6-year period from CY 2010 through CY 2015 will be a cost of \$596.58 million.

Many of the new requirements involve clarifications of existing regulations and policies. As such, they should help plans to improve their administrative operational functions which will streamline the Medicare Prescription Drug program and strengthen beneficiary protections within the program. Specifically, we believe that the proposed requirements will improve coordination of care, increase quality of data reporting, increase ability to comply with existing regulations and policies, enhance appeal and grievance procedures, and curtail illegal marketing practices. Additional benefits include clarification of timeframes and notification requirements. Some of the new requirements may lead to changes in health plan service areas.

We anticipate that several of the proposed requirements will be beneficial to PBMs when assisting Part D sponsors with administering the Part D benefit. Proposed codification of transition process requirements and establishment of protected classes will assist PBMs in applying the Part D requirements consistently across Part D plans and managing the Part D sponsor's benefit packages more efficiently. Establishing cut-off limits for coordination of benefits and requiring Part D sponsors to report other payer information in a timely fashion to CMS' COB contractors will improve the administrative burden of the payment

reconciliation process. The technical correction to the definition of gross covered prescription drug costs will also help PBMs with calculating a beneficiary's gross covered prescription drug costs.

D. Analysis by Provision

With regard to part 422, Risk Adjustment Data Validation (RADV), we estimate that we will audit approximately 110 MA organizations for risk adjustment data validation (RADV) in FYs 2010 and 2011. We estimate that at least 50 percent of these organizations—55 MA organizations—will pursue one of the options presented in these proposed rules for disputing or appealing their RADV audit findings—via attestation, documentation dispute, or RADV payment error calculation appeal. Our experience to date indicates that approximately 25 percent of HCCs audited under RADV audit procedures result in signature and credential-related medical record review errors. Each MA organization that undergoes a RADV audit is on average asked to validate approximately 700 HCCs for 200 beneficiaries selected for audit.

Since signature and credential-related errors comprise such a large overall percentage of RADV error, there is clearly an incentive for MA organizations to submit attestations along with medical records missing signatures/credentials to avoid incurring a RADV audit error. With approximately 110 organizations expected to undergo RADV audit annually, we can estimate that MA organizations will seek to produce roughly 19,250 attestations (or 175 attestations per audit). We estimate that it will take 1 hour to prepare and submit one attestation to CMS. This

equates to 19,250 burden hours at approximately \$59.20/hour (based on U.S. Department of Labor statistics for hourly wages for management analysts)—or, an aggregate annual dollar burden on the MA industry of \$1,139,600. RADV audit statistics to date indicate that approximately 55 percent of RADV audit errors are of the type that may be eligible for documentation dispute. Clearly there is a financial incentive for MA organizations to pursue documentation dispute in an attempt to avoid incurring a RADV audit error. Utilizing the same statistics regarding the number of organizations that we expect to undergo RADV audit annually (that is, 110 organizations), we estimate that 100 percent of these organizations will pursue documentation dispute. Each MA organization that undergoes RADV audit is on average asked to validate approximately 700 HCCs for 200 beneficiaries audited. Therefore, we can expect each organization that undergoes RADV audit to pursue documentation dispute for 385 HCCs. This equates to an overall volume of 42,350 document dispute requests annually. We estimate that it will take approximately 1 hour to prepare the necessary documentation to dispute one HCC via documentation dispute. This equates to 42,350 burden hours at approximately \$59.20/hour (based on U.S. Department of Labor (DOL) statistics for hourly wages for management analysts) or an aggregate annual dollar burden on the MA industry of \$2,507,120.

Finally, regarding requests for RADV payment error calculation appeals, based upon existing RADV audit data, we estimate that 100 percent of MA organizations that undergo RADV audit

We are also proposing to require in § 422.152 that each MAO contract conduct CCIPs in patient populations and quality improvement projects in areas identified by CMS and also collect and report new quality measures. The mean estimated burden per contract as indicated in section III. of this proposed rule is 1,000 hours. The estimated mean cost per hour for these contracts is \$59.20 (wages, fringe benefits, and overhead). The mean cost per contract is: $1,000 \times \$59.20 = \$59,200$. Since the number of contracts is estimated to be 624, the overall estimated cost across all contracts is: $624 \times \$59,200 = \$36,940,800$.

Regarding the Medicare Secondary Payer (MSP) Procedures (§ 422.108), in 2007 original Medicare estimated total savings due to MSP at \$6.5 billion. This included \$2.9 billion recovered or avoided for working-aged individuals, \$1.9 billion for working-disabled individuals, \$877 million for workers' compensation, \$278 million for ESRD beneficiaries, and another \$485 million recovered or avoided for liability and other insurers. In 2007, there were approximately 8.5 million MA enrollees and 44 million total Medicare enrollees (an MA penetration rate of approximately 19 percent). The \$6.5 billion in MSP savings can be attributed to 35.5 million original Medicare enrollees, which equates to approximately \$183 per original Medicare enrollee that can be attributed to MSP savings. In 2009 MA penetration is higher, with approximately 11 million MA enrollees out of approximately 45 million total Medicare enrollees—or about 24 percent MA penetration. We assume a similar MSP rate for MA enrollees as obtains in original Medicare, and therefore project total savings from MSP in the MA program in 2007 as close to \$1.5 billion and by 2010 at approximately \$2 billion.

The estimated impact of MSP on 624 MA organizations and 456 PDPs based on 3.1158 million burden hours at approximately \$25/hour (based on U.S. Department of Labor (DOL) statistics for the hourly wages of claims analysts of \$22.20/hour and for management analysts of \$59.20/hour), is approximately \$77.9 million. We expect an MA organization to use approximately 1.5 FTEs to implement Part C MSP procedures related to avoiding costs, reporting data, and collecting from liable third parties related to MSP. We expect the work mix to be completed approximately 90 percent by the claims analyst and 10 percent by the management analyst.

We note that MAOs claim expenses related to MSP recoveries as part of their

administrative overhead. MA organizations that faithfully pursue and recover from liable third parties will have lower medical expenses. Lower medical expenses make such plans more attractive to enrollees. The lower the medical expenses in an MA plan, the higher the potential rebate. The rebate is calculated as the difference between the cost of Medicare benefits and the benchmark for that plan. The benchmark is a fixed amount. Therefore, as the cost of Medicare benefits go down (with the benchmark remaining constant), the larger the rebate. Therefore, as more MSP dollars are collected or avoided, medical expense go down and rebates go up, allowing the sponsoring MA organization to offer potential enrollees additional non-Medicare benefits funded by rebate dollars. Such non-Medicare benefits include reductions in cost sharing. Since cost sharing is generally expressed as a percentage of medical costs, such cost sharing will also be proportionally lower as overall medical costs go down—providing MA organizations offering such plans with an additional competitive edge.

Regarding validation of reporting requirements (§ 422.516 and § 423.514), the main focus will be on how the sponsor collects, stores, and reports the new Part C and Part D data requirements. Standards and procedures will also focus on how sponsors compile data, and verify calculations, computer code, and algorithms. The estimated mean hourly burden per affected part C and Part D sponsor to procure an auditing organization and to support the auditing organization in its data collection efforts including staff interviews is 120 hours as indicated in section III. of this proposed rule. We believe the auditor that is hired by the plan will typically have a team consisting of a management analyst, two senior auditors, a senior claims analyst, a senior statistician, an IT systems analyst, a computer programmer, and a word processor. We used May 2008 wage statistics supplied by the Department of Labor, Bureau of Labor Statistics to develop estimates of direct wages. We also added fringe benefits, overhead costs, and general and administrative expenses using percentages that are consistent with CMS contracts. Based on our experience and in consultant with program experts, we developed an estimate of the hourly burden. The estimated mean cost per hour for these sponsors is \$43.14 (wages, fringe benefits, and overhead). The estimated mean number of hours per sponsor is 120. The mean cost per

sponsor to procure and support the auditor is therefore: $120 \times \$43.14 = \$5,177$. Since the number of sponsors is estimated to be 710, the overall estimated cost across all sponsors to do the work involved in procuring and supporting the auditing contractors is: $710 \times \$5,177 = \$3,675,670$.

The total estimated burden hours related to the time and effort for all auditing organizations to perform the annual audit for both Part C and Part D data validation is estimated to be 215,840. The mean cost per hour (includes direct wages, fringe benefits, overhead costs, general and administrative expenses, and fee) is estimated to be \$194.21. Therefore, the estimated annual cost for auditing contracts involving all 710 sponsors is: $215,840 \times \$194.21 = \$41,918,287$. The total estimated annual cost for auditing contracts and for the procurement and audit support time and effort of the sponsors is: $\$41,918,287 + 3,675,670 = \$45,593,956$. The auditing costs will be allowable costs in the plan's bid.

We are also proposing that beginning in 2011 MA organizations and Part D sponsors will begin paying for the data collection costs of the CAHPS annual survey. Data collection is to be performed by a contractor hired by the MAO or part D sponsor. The mean estimated burden per contract as indicated in section III. of this proposed rule is 51 hours. The estimated mean cost per contract is \$5,023. The overall estimated annual cost across 624 contracts is: $624 \times \$5,023 = \$3,134,352$.

Regarding written notices of a favorable standard coverage determination (§ 423.568(d)), the burden is the time and effort necessary for each of an estimated 456 PDP sponsors to disclose the necessary information in writing to an enrollee. (Note: plan sponsors have always been required to formulate a decision and notify the enrollee of that decision, so the additional burden is only related to communicating the favorable decision in writing). We estimated an annual burden of 380,206 hours. At an estimated cost of \$40.00 per hour (salary/wages, fringe benefits, overhead), the estimated total annual cost of this proposed change is \$15,208,240.

The burden associated with providing written notice of a favorable expedited coverage determination (§ 423.572(b)) is the time and effort necessary for each of an estimated 456 PDP sponsors to disclose the necessary information in writing to an enrollee (given that plan sponsors have always been required to formulate favorable and adverse expedited decisions, notify enrollees of

those decisions, and follow-up in writing if the decision is adverse, the additional burden is only related to communicating the favorable decision in writing).

The total estimated annual burden associated with this requirement was 43,550 hours. At an estimated cost of \$40.00 per hour, the estimated total annual cost of this proposed change is \$1,742,000. Therefore, the total estimated annual cost for these two provisions is \$15,208,240 + \$1,742,000 = \$16,950,240. The total estimated annual cost for years 2010–2015 is \$102 million.

Additionally, regarding written notices, proposed § 423.590(d)(2) states that if a Part D plan sponsor first notifies an enrollee of an adverse or favorable expedited redetermination decision orally, it must mail written confirmation to the enrollee within 3 calendar days of the oral notification. The burden associated with this requirement is the time and effort necessary for a Part D plan sponsor to notify an enrollee (and the prescribing physician or other prescriber involved, as appropriate) in writing of an adverse or favorable expedited redetermination decision. We estimate that each year the 456 Part D plan sponsors will issue a total of about 21,232 written adverse and favorable expedited notifications. We further estimate that it will take a Part D plan sponsor 30 minutes to distribute a single notice. The estimated annual burden associated with the requirement in § 423.590(d)(2) is 10,616 hours. At an estimated cost of \$40.00 per hour, the estimated total annual cost of this proposed change is \$424,640. The total estimated annual cost for years 2010–2015 is \$2.5 million.

With regard to standard timeframes and notice requirements for organization determinations (§ 422.568 and § 423.568), the total estimated annual burden is 380,206 hours. At an estimated average hourly cost of \$40.00, the total annual estimated cost for CY 2010 is \$15,208,240.

Regarding the MIPPA 176 protected drug class provisions, we project that future utilization and hence future costs will be lower than estimated in the Medicare Advantage and Prescription Drug Programs: MIPPA–Related Marketing Revisions interim final rule with comment period published in the January 16, 2009 Federal Register (74 FR 2881). This is because the proposed provisions may be somewhat more restrictive than those in the January 16, 2009 IFC. That is, in the January 16, 2009 IFC, we had not proposed definitions of associated with MIPPA protected classes criteria. The

definitions, as outlined in this proposed rule, provide further precision with respect to the MIPPA criteria leading to a reduced likelihood of certain disease categories qualifying as protected classes.

The FY 2010 President's Budget estimated cost of this provision was about \$4.9 billion for FYs 2010 through 2019. This is the amount that was built into our FY 2010 budget projections. The revised cost estimate is roughly \$1.6 billion over the same period. As a result, the modifications made in the rule will save Part D an estimated \$3.3 billion for FYs 2010 through 2019 relative to our current Budget baseline.

Regarding the Transition Process (§ 423.120), proposed § 423.120 would require sponsors to provide enrollees with appropriate notice regarding their transition process within a reasonable amount of time after providing a temporary supply of non-formulary Part D drugs (including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a sponsor's utilization management rules). We estimated the annual hourly burden to be 337,500 hours in section III. of this proposed rule. At an estimated average \$20 cost per hour for the fully loaded labor of an administrative assistant, we estimate the yearly cost to be \$6,750,000 in CY 2010.

Regarding drug utilization management, quality assurance, and medication therapy management programs (MTMPs), proposed § 423.153 states that Part D plans must offer a minimum level of medication therapy management services for each beneficiary enrolled in the MTMP that includes but is not limited to annual comprehensive medication reviews with written summaries. We estimated that the total annual burden associated with this requirement is 937,500 hours. At an average cost of \$120 per hour, we estimate the yearly cost to be \$112,500,000.

Regarding the Use of Standardized Technology under Part D (§ 423.120) requirements, we estimated an annual burden of 38,640 hours, with a cost of \$150 per hour. The estimated one time cost impact for CY 2010 is \$5.80 million.

E. Anticipated Effects

1. Effects of Cap on Out-of-Pocket Costs and Cost Sharing Amounts

We are proposing to establish and require local MA plans to have an annual catastrophic cap on members out-of-pocket cost sharing and that we will also establish limits on the cost sharing amounts that MA plans can

impose for Part A and B services. These proposed changes are significant in that they will help beneficiaries to understand and anticipate their possible health care expenditures. However, we do not believe these changes will by themselves have a significant impact on either plan participation or plan costs. We will set the parameters for the cost sharing and spending cap and this should make it easier for MA plans to compete on a level playing field and as previously noted enhance transparency for prospective enrollees. We note that while there will be cost sharing limits and a catastrophic cap. We are not setting a cap on the monthly plan premium beyond the overall actuarial limit (determined annually by CMS) on the amount of cost sharing that MA plans may impose on its enrollees. In other words, MA plans will still have the option of collecting the maximum allowed actuarial amount of cost sharing from beneficiaries in terms of premium, and costs sharing amounts for plan covered benefits.

2. Alternatives Considered

a. Strengthening CMS' Ability To Take Timely, Effective Contract Determinations or Intermediate Sanctions (Part C & D)

We are proposing to modify the regulations to more clearly and accurately clarify our existing statutory authority to terminate a contract. The existing enumerated list of determinations that could support a decision to terminate a contract is not all inclusive. Therefore, we are proposing to remove the enumerated list. Also, we are proposing to revise the regulatory language to clarify that failure to comply with any of the regulatory requirements contained in parts 422 and 423 or failure to meet our performance requirements, may constitute a basis for CMS to determine that the MA Organization or Part D sponsor meets the requirements for contract termination in accordance with the statutory standard. We considered modifying or adding to the existing list of determinations that could support termination (which included 12 items in parts 422 and 11 items in parts 423). However, we believe that continuing to add to the existing list may fail to make sufficiently clear to sponsoring organizations that all violations of our regulations and/or contract and performance requirements may be used to support a termination decision.

b. Changing the Standards of Review, Clarifying the Standard of Proof and Burden of Proof for Appeals, and Modifying the Conduct of Hearing for Contract Decisions (Including Denials of Initial Applications to Contract, Service Area Expansions for Existing Contracts, Contract Non-Renewals and Terminations, and Intermediate Sanctions)

We are proposing to change the standards of review and clarify the standard of proof when an appeal of a contract determination or intermediate sanction is requested and an evidentiary hearing is conducted. The current standards of review require the hearing officer to determine whether the sponsoring organization can demonstrate “substantial compliance” with Part C and/or Part D requirements on the “earliest of” the following three dates: The date the organization received written notice of contract determination or intermediate sanction, the date of the most recent onsite audit, or the date of the alleged breach of current contract or past substantial noncompliance. In practice, these standards of review (“substantial compliance” and “earliest of test”) have led to confusion among parties to the hearing and have been difficult for the hearing officer to apply. Additionally, though the existing regulations explicitly state that the sponsoring organization bears the burden of proof, it does not provide the standard of proof that is to be applied by the hearing officer. Therefore, we are proposing to delete the “substantial compliance” and “earliest of” test and revise the regulations to explicitly state the standard of proof and provide clear standards of review for each type of contract determination or intermediate sanction.

First, we are proposing to explicitly state that the hearing officer must apply the “preponderance of the evidence” standard of proof when weighing the evidence at all hearings for contract determinations or intermediate sanctions. Second, we are proposing to clarify the standards of review, which vary according to the type of contract determination or intermediate sanction. In particular, the proposed change makes the distinction between how the evidentiary standard of review is to be applied to appeals of CMS determinations involving Part C or D contract qualification applications, those involving the termination or non-renewal of a Part C or D sponsor contract, and those involving the imposition of intermediate sanctions. Finally, we are proposing to clarify that

because the sponsoring organization bears the burden of proof, under any briefing schedule determined by the hearing officer, it must first present evidence and argument to the hearing officer before we present our evidence and argument. We considered leaving the existing regulations unchanged.

c. Clarify That CMS May Require a “Test Period” During an Enrollment/Marketing Sanction

We are proposing to provide that in instances where an enrollment and/or marketing suspension has been imposed, we may determine that it is appropriate to subject the MA organization or Part D sponsor to a “test period” whereby the organization or sponsor will, for a limited time, engage in marketing activities and/or accept enrollments in order to assist us in making a determination as to whether the bases for the sanctions have been corrected and are not likely to recur. Currently, our experience has shown that we are limited in our ability to adequately determine if marketing and enrollment deficiencies have been corrected while marketing and enrollment sanctions are in place. If the test of the Part D sponsor or MA organization’s marketing/enrollment processes reveals that deficiencies have not been corrected and/or are likely to recur, the sanction will continue to remain in place.

We considered leaving the existing regulations unchanged. However, we believe this proposal will strengthen our ability to adequately assess compliance with our requirements. The proposal will also help us to avoid situations where, because we do not have the ability to perform adequate testing of an organization’s systems/processes (such as information systems testing) to ensure the deficiencies have been corrected, we lift a sanction and then find that we have to re-engage in the statutory and regulatory process for reinstating the sanction.

d. Right for CMS To Require an Independent Audit of Sponsoring Organizations Under Intermediate Sanction

We are proposing that we have the flexibility to require certain Part D sponsors and MA organizations, under intermediate sanctions, to hire an independent auditor to evaluate whether the bases for a sanction have been corrected and are not likely to recur before we come to a determination as to whether lifting of the sanction would be appropriate. The independent auditor would be hired by the sponsoring organization and work in

accordance with CMS specifications in order to provide accurate and reliable information to CMS. This would benefit the sponsoring organization by improving the process for removing a sanction, which may reduce the duration of the sanction. A similar approach is used by the Office of Inspector General (OIG) in their Corporate Integrity Agreements and/or Self-Disclosure Protocol processes.

We considered leaving the regulations unchanged. This existing regulatory scheme requires us to rely solely on its internal resources to assess whether the underlying deficiencies that form the basis of an intermediate sanction have been corrected and are not likely to recur. Given our experience with the nature and extent of some compliance deficiencies (for example, those caused by information technology issues or lack of adequate internal controls) and the need to obtain the level of skill and experience necessary to conduct an exhaustive audit and verification of the correction of these deficiencies, we believe this additional flexibility and access to expertise (such as a qualified independent auditor) is appropriate and will benefit both plan sponsors and CMS.

Another option considered is not requiring certain sponsoring organizations to hire an independent auditor. Instead, we would consider using results obtained by an independent auditor hired under a sponsoring organization’s own initiative to evaluate its compliance with our requirements. We may consider the sponsoring organization’s initiative to obtain an independent audit similar to a “safe harbor” and may be afforded some weight in CMS’ determination of whether the bases for the sanction have been corrected and are not likely to recur. We invite comments from sponsors and the industry about this alternative proposal and suggestions on other options we could implement to accomplish the desired outcome.

e. The Ability for CMS To Require Sponsors To Disclose to Current and Potential Enrollees Compliance and Performance Deficiencies

We are proposing to require certain sponsors to disclose their current compliance and/or performance deficiencies to existing and potential enrollees. This disclosure option could be exercised by CMS either when a sponsor is sanctioned or when a sponsor’s compliance deficiencies rise to a certain level such that we make the determination that existing or potential enrollees should be notified of these deficiencies. This level of transparency

will provide additional incentives for sponsors to make improvements to their operations and also provide relevant information to beneficiaries and the public concerning plan choices.

We considered not adding this disclosure authority to the existing regulations. However, we believe this change is necessary to provide us with another tool to strengthen our compliance and oversight authority and provide appropriate transparency concerning compliance and/or performance deficiencies to beneficiaries and the public.

f. Section 176 of the MIPPA—Formulary and Protected Classes Requirements (Part D)

The critical policy decision was how broadly or narrowly we interpret specific terms in the MIPPA provisions. Interpreted broadly, the provisions in section 176 of the MIPPA might easily encompass many classes of drugs and significantly increase costs to the Part D program by eliminating the need for manufacturers to aggressively rebate their products for formulary placement. Only a narrow interpretation of these criteria would limit the number of classes “protected” under MIPPA.

g. Reducing Duplicative and Low Enrollment Plans (Parts C & D)

We are proposing to implement regulations to reduce duplicative benefit packages based upon our authority to add such additional terms to its contracts with Medicare Advantage organizations or Part D plan sponsors as we “may find necessary and

appropriate” as specified in section 1857(e)(1) of the Act (see also section 1860D–12(b)(3)(D) of the Act (incorporating section 1857(e)(1) of the Act by reference for Part D.) In addition, we are using our authority under section 1860D–11(d)(2)(B) of the Act as further support for our authority to propose regulations imposing “reasonable minimum standards” on Part D sponsors.

One alternative would be to make no changes to our current regulations regarding bid submission and review and to continue our current efforts to eliminate duplicative or low enrollment plan options. However, since our current regulations do not explicitly address the issue of eliminating duplicative or low enrollment plans, we believe that codifying our authority to do so will provide us with more leverage over plans during the bid submissions, review, negotiation, and approval processes.

Another alternative would be to provide more detail in regulation text regarding the specific criteria we would use to eliminate duplicative or low enrollment plan options. We believe addressing the issue generally in regulations text, but containing most of the discussion regarding specific criteria to the preamble, maintains our flexibility to adjust our review processes and criteria consistent with current market trends.

h. Validation of Part C and Part D Reporting Requirements

Several of the proposed changes do involve costs to MAOs and Part D

sponsors. One such regulatory change was the audit requirement of Part C and Part D measures. We considered not requiring an audit. However, because we believe that an audit is required to ensure that the Part C and Part D measures are consistent with our specifications, are reliable, valid, and comparable, and are credible to stakeholders, this alternative was rejected. A second such regulatory change was requiring MAOs and Part C sponsors to assume a portion of the cost of the annual CAHPs survey that would result from hiring contractors to conduct the data collection. We considered not requiring MAOs and Part C sponsors to hire contractors to perform the CAHPs data collection. However, we rejected this alternative, because we believe that the benefits obtained through this regulatory change outweigh the costs incurred by the MAOs and Part C sponsors.

F. Accounting Statement

As required by OMB Circular A–4 (available at <http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf>), in the Table 13, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule. Table 13 provides our best estimate of the costs and savings as a result of the changes.

TABLE 13—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM CY 2010 TO CY 2015
[\$ in millions]

Category	Transfers			
	Year dollar	Units discount rate		Period covered
		7%	3%	
Annualized Monetized Transfers	2009	\$–204.45	\$–213.23	CYs 2010–2015
From Whom to Whom?	Federal Government to MAO and Part D Sponsors.			
Annualized Costs to MAOs and Part D Sponsors	2009	\$319.51	\$319.46	CYs 2010–2015

G. Conclusion

We expect that the cost of implementing these provisions will be \$321.68 million in CY 2010. Sponsors will experience additional costs which they are likely to pass on to us through direct subsidy payments and to beneficiaries through increases in premiums as reflected in their bids. Beginning in CY 2013, we expect that these provisions will generate a net

savings on an annual basis. For the entire estimated time period, CY 2010 through 2015, we expect the overall impact to be a cost of \$596.58 million.

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 417

Administrative practice and procedure, Grant programs—health, Health care, Health insurance, Health maintenance organizations (HMO), Loan programs—health, Medicare, and Reporting and recordkeeping requirements.

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health Maintenance Organizations (HMO), Medicare, Penalties, Privacy, and Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 480

Health care, Health professions, Health records, Peer Review Organizations (PRO), Penalties, Privacy, and 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 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

1. The authority citation for part 417 continues to read as follows:

Authority: Sec. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), secs. 1301, 1306, and 1310 of the Public Health Service Act (42 U.S.C. 300e, 300e–5, and 300e–9), and 31 U.S.C. 9701.

Subpart K—Enrollment, Entitlement, and Disenrollment Under Medicare Contract

2. Section 417.428 is revised to read as follows:

§ 417.428 Marketing activities.

(a) With the exception of § 422.2276 of this chapter, the procedures and requirements relating to marketing requirements set forth in subpart V of part 422 of this chapter also apply to Medicare contracts with HMOs and CMPs under section 1876 of the Act.

(b) In applying those provisions, references to part 422 of this chapter must be read as references to this part, and references to MA organizations as references to HMOs and CMPs.

Subpart L—Medicare Contract Requirements

3. Section 417.472 is amended by adding paragraphs (i) and (j) to read as follows:

§ 417.472 Basic contract requirements.
* * * * *

(i) The HMO or CMP must comply with the requirements at § 422.152(b)(5).

(j) All coordinated care contracts (including local and regional PPOs and contracts with exclusively SNP benefit packages, cost contracts under section 1876 of the Act, private fee-for-service contracts, and MSA contracts with 600 or more enrollees in July of the prior year) must contract with approved Medicare Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey vendors to conduct the Medicare CAHPS satisfaction survey of MA plan enrollees in accordance with CMS specifications and submit the survey data to CMS.

4. Section 417.492 is amended by revising paragraph (b)(2) to read as follows:

§ 417.492 Nonrenewal of contract.

* * * * *

(b) * * *

(2) *Notice of appeal rights.* CMS gives the HMO or CMP written notice of its right to appeal the nonrenewal decision, in accordance with part 422 subpart N of this chapter, if CMS's decision was based on any of the reasons specified in § 417.494(b).

5. Section 417.494 is amended by revising paragraph (b)(2) to read as follows:

§ 417.494 Modification or termination of contract.

* * * * *

(b) * * *

(2) If CMS decides to terminate a contract, it sends a written notice informing the HMO or CMP of its right to appeal the termination in accordance with part 422 subpart N of this chapter.

* * * * *

6. Section 417.500 is revised to read as follows:

§ 417.500 Intermediate sanctions for and civil monetary penalties against HMOs and CMPs.

(a) Except as provided in paragraph (c) of this section, the rights, procedures, and requirements related to intermediate sanctions and civil money penalties set forth in part 422 subparts O and T of this chapter also apply to Medicare contracts with HMOs or CMPs under sections 1876 of the Act.

(b) In applying paragraph (a) of this section, references to part 422 of this chapter must be read as references to this part and references to MA organizations must be read as references to HMOs or CMPs.

(c) In applying paragraph (a) of this section, the amounts of civil money penalties that can be imposed are governed by section 1876(i)(6)(B) and

(C) of the Act, not by the provisions in part 422 of this chapter.

Subpart O—Medicare Payment: Cost Basis

7. Section 417.564 is amended by adding new paragraphs (b)(2)(iii) and (c) to read as follows:

§ 417.564 Apportionment and allocation of administrative and general costs.

* * * * *

(b) * * *

(2) * * *

(iii) For the costs incurred under paragraphs (b)(1)(i) through (iv) of this section that include personnel costs, the organization must be able to identify the person hours expended for each administrative task and the rate of pay for those persons performing the tasks. Administrative tasks performed and rate of pay for the persons performing those tasks must match in terms of the skill level needed to accomplish those tasks. This information must be made available to CMS upon request.

(c) *Costs excluded from administrative costs.* In accordance with section 1861(v) of the Act, the following costs must be excluded from administrative costs:

- (1) Donations.
- (2) Fines and penalties.
- (3) Political and lobbying activities.
- (4) Charity or courtesy allowances.
- (5) Spousal education.
- (6) Entertainment.
- (7) Return on equity.

Subpart R—Medicare Contract Appeals

8. Section § 417.640 is revised to read as follows:

§ 417.640 Applicability.

(a) The rights, procedures, and requirements relating to contract determinations and appeals set forth in part 422 subpart N of this chapter also apply to Medicare contracts with HMOs or CMPs under section 1876 of the Act.

(b) In applying paragraph (a) of this section, references to part 422 of this chapter must be read as references to this part and references to MA organizations must be read as references to HMOs or CMPs.

§ 417.642 through § 417.694 [Removed]

9. Remove § 417.642 through § 417.694.

Subpart U—Health Care Prepayment Plans

10. Section 417.840 is revised to read as follows:

§ 417.840 Administrative review procedures.

The HCPP must apply § 422.568 through § 422.626 of this chapter to—
(a) Organization determinations and fast-track appeals that affect its Medicare enrollees; and
(b) Reconsiderations, hearings, Medicare Appeals Council review, and judicial review of the organization determinations and fast-track appeals specified in paragraph (a) of this section.

PART 422—MEDICARE ADVANTAGE PROGRAM

11. The authority citation for part 422 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart A—General Provisions

- 12. Section 422.2 is amended by—
 - A. Adding the definitions of “Attestation process,” “documentation dispute process,” and “Hierarchical condition categories.”
 - B. Revising the definition of “Point of service.”
 - C. Adding the definitions of “RADV payment error calculation appeal process” and “Risk adjustment data validation (RADV) audit.”
 - D. Revising the introductory text of the definition of “Service area”.
 - E. Adding the definition of “The one best medical record”.

The additions and revision read as follows:

§ 422.2 Definitions.

Attestation process means a CMS-developed RADV audit-related dispute process that enables MA organizations undergoing RADV audit to submit CMS-generated and physician practitioner signed attestations for medical records with missing or illegible signatures or credentials. Physicians/practitioners who documented health care services in the specific medical record under RADV review will be allowed to attest that they provided and documented the health care services evidenced in the specific medical record.

* * * * *

Documentation dispute process means a dispute process that enables MA organizations that have undergone a RADV audit to dispute medical record discrepancies that pertain to incorrect ICD–9–CM coding by allowing affected MA organizations to submit formal written disputes regarding discrepancy findings for the initial medical record

that an organization submitted for HCC validation.

* * * * *

Hierarchical condition categories (HCC) means disease groupings consisting of disease codes (currently ICD–9–CM codes) that predict average healthcare spending. HCCs represent the disease components of the enrollee risk score that are applied to MA payments.

* * * * *

Point of service (POS) means a benefit option that an MA HMO plan can offer to its Medicare enrollees as an additional, mandatory supplemental, or optional supplemental benefit. Under the POS benefit option, the HMO plan allows members the option of receiving specified services outside of the HMO plan’s provider network. In return for this flexibility, members typically have higher cost-sharing requirements for services received and, when offered as a mandatory or optional supplemental benefit, may also be charged a premium for the POS benefit option.

* * * * *

RADV payment error calculation appeal process means an administrative process that enables MA organizations that have undergone RADV audit to appeal the CMS calculation of an MA organization’s RADV payment error.

* * * * *

Risk adjustment data validation (RADV) audit means a CMS-administered payment audit of a Medicare Advantage (MA) organization that ensures the integrity and accuracy of risk adjustment payment data.

* * * * *

Service area means a geographic area that for local MA plans is a county or multiple counties, and for MA regional plans is a region approved by CMS within which an MA-eligible individual may enroll in a particular MA plan offered by an MA organization. Facilities in which individuals are incarcerated are not included in the service area of an MA plan. Each MA plan must be available to all MA-eligible individuals within the plan’s service area. In deciding whether to approve an MA plan’s proposed service area, CMS considers the following criteria: * * *

* * * * *

The one best medical record for the purposes of Medicare Advantage Risk Adjustment Validation (RADV) is defined as: the clinical documentation for a single encounter for care (that is, a physician office visit, an inpatient hospital stay, or an outpatient hospital visit) that occurred for one patient during the data collection period. The single encounter for care must be based

on a face-to-face encounter with a provider deemed acceptable for risk adjustment and documentation of this encounter must be reflected in the medical record.

- 13. Amend § 422.4 by—
 - A. Revising paragraphs (a)(1)(v) and (a)(2)(i)(A).
 - B. Redesignating paragraph (a)(2)(i)(B) as paragraph (a)(2)(i)(C).
 - C. Adding new paragraphs (a)(2)(i)(B) and (a)(3)(iv).

The revisions and additions read as follows:

§ 422.4 Types of MA plans.

* * * * *

- (a) * * *
- (1) * * *
- (v) A PPO plan is a plan that—
 - (A) Has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan;
 - (B) Provides for reimbursement for all covered benefits regardless of whether the benefits are provided within the network of providers;
 - (C) Only for purposes of quality assurance requirements in § 422.152(e), is offered by an organization that is not licensed or organized under State law as an HMO; and
 - (D) Does not permit prior notification for out-of-network services—that is, a reduction in the plan’s standard cost-sharing levels when the out-of-network provider from whom an enrollee is receiving plan-covered services voluntarily notifies the plan prior to furnishing those services, or the enrollee voluntarily notifies the PPO plan prior to receiving plan-covered services from an out-of-network provider.
- (2) * * *
- (i) * * *
- (A) Pays at least for the services described in § 422.101, after the enrollee has incurred countable expenses (as specified in the plan) equal in amount to the annual deductible specified in § 422.103(d);
- (B) Does not permit prior notification—that is, a reduction in the plan’s standard cost-sharing levels when the provider from whom an enrollee is receiving plan-covered services voluntarily notifies the plan prior to furnishing those services, or the enrollee voluntarily notifies the MSA plan prior to receiving plan-covered services from a provider; and
- (3) * * *
- (iv) Does not permit prior notification—that is, a reduction in the plan’s standard cost-sharing levels when the provider from whom an enrollee is receiving plan-covered services

* * * * *

voluntarily notifies the plan prior to furnishing those services, or the enrollee voluntarily notifies the PFFS plan prior to receiving plan-covered services from a provider.

* * * * *

Subpart B—Eligibility, Election, and Enrollment

14. Section 422.74 is amended by revising paragraphs (d)(1)(i)(B) and (d)(4)(iii) to read as follows:

§ 422.74 Disenrollment by the MA organization.

* * * * *

(d) * * *

(1) * * *

(i) * * *

(B) Providing the individual with a grace period, that is, an opportunity to pay past due premiums in full. The length of the grace period must be at least 2 months, beginning on the first day of the month for which the premium is unpaid.

* * * * *

(4) * * *

(iii) *Exception.* If the MA plan offers a visitor/traveler benefit when the individual is out of the service area but within the United States (as defined in § 400.200 of this chapter) for a period of consecutive days longer than 6 months but less than 12 months, the MA organization may elect to offer to the individual the option of remaining enrolled in the MA plan if—

(A) The individual is disenrolled on the first day of the 13th month after the individual left the service area (or residence, if paragraph (d)(4)(i)(B) of this section applies);

(B) The individual understands and accepts any restrictions imposed by the MA plan on obtaining these services while absent from the MA plan's service area for the extended period, consistent with paragraph (d)(4)(i)(C) of the section;

(C) The MA organization makes this visitor/traveler option available to all Medicare enrollees who are absent for an extended period from the MA plan's service area. MA organizations may limit this visitor/traveler option to enrollees who travel to certain areas, as defined by the MA organization, and who receive services from qualified providers who directly provide, arrange for, or pay for health care; and

(D) The MA organization furnishes all Medicare Parts A and B services and all mandatory and optional supplemental benefits at the same cost sharing levels as apply within the plan's service area; and

(E) The MA organization furnishes the services in paragraph (D) of this

paragraph consistent with Medicare access and availability requirements at § 422.112 of this part.

* * * * *

Subpart C—Benefits and Beneficiary Protections

15. Section 422.100 is amended by adding new paragraphs (f)(4) and (f)(5) to read as follows:

§ 422.100 General requirements.

* * * * *

(f) * * *

(4) All local MA plans must establish an out-of-pocket maximum for Medicare A and B services that is no greater than the annual limit set by CMS.

(5) Cost sharing for Medicare A and B services does not exceed levels annually determined by CMS to be discriminatory.

* * * * *

16. Section 422.103 is amended by adding a new paragraph (d)(3) to read as follows:

§ 422.103 Benefits under an MA MSA plan.

* * * * *

(d) * * *

(3) Is pro-rated for enrollments occurring during a beneficiary's initial coverage election period as described at § 422.62(a)(1) of this part.

* * * * *

17. Section 422.105 is amended by revising paragraphs (b), (c), and (f) to read as follows:

§ 422.105 Special rules for self-referral and point of service option.

* * * * *

(b) *Point of service option.* As a general rule, a POS benefit is an option that an MA organization may offer in an HMO plan to provide enrollees with additional choice in obtaining specified health care services. The organization may offer A POS option—

(1) Before January 1, 2006, under a coordinated care plan as an additional benefit as described in section 1854(f)(1)(A) of the Act;

(2) Under an HMO plan as a mandatory supplemental benefit as described in § 422.102(a); or

(3) Under an HMO plan as an optional supplemental benefit as described in § 422.102(b).

(c) *Ensuring availability and continuity of care.* An MA HMO plan that includes a POS benefit must continue to provide all benefits and ensure access as required under this subpart.

* * * * *

(f) *POS-related data.* An MA organization that offers a POS benefit

through an HMO plan must report enrollee utilization data at the plan level by both plan contracting providers (in-network) and by non-contracting providers (out-of-network) including enrollee use of the POS benefit, in the form and manner prescribed by CMS.

18. Section 422.108 is amended by revising paragraph (b)(3) to read as follows:

§ 422.108 Medicare secondary payer (MSP) procedures.

* * * * *

(b) * * *

(3) Coordinate its benefits to Medicare enrollees with the benefits of the primary payers, including reporting, on an ongoing basis, information obtained related to requirements in paragraphs (b)(1) and (b)(2) of this section in accordance with CMS instructions.

* * * * *

19. Section 422.111 is amended by adding a new paragraph (g) to read as follows:

§ 422.111 Disclosure requirements.

* * * * *

(g) CMS may require an MA organization to self-disclose to its enrollees or potential enrollees, the MA organization's performance and contract compliance deficiencies in a manner specified by CMS.

20. Section 422.112 is amended by adding a new paragraph (a)(10) to read as follows:

§ 422.112 Access to services.

* * * * *

(a) * * *

(10) *Prevailing patterns of community health care delivery.* Coordinated care and PFFS MA plans that meet Medicare access and availability requirements through direct contracting network providers must do so consistent with the prevailing community pattern of health care delivery in the areas where the network is being offered. Factors making up community patterns of health care delivery that CMS will use as a benchmark in evaluating a proposed MA plan health care delivery network include, but are not limited to—

(i) The number and geographical distribution of eligible health care providers available to potentially contract with an MAO to furnish plan covered services within the proposed service area of the MA plans.

(ii) The prevailing market conditions in the service area of the MA plan. Specifically, the number and distribution of health care providers contracting with other health care plans (both commercial and Medicare) operating in the service area of the plan.

(iii) Whether the service area is comprised of rural or urban areas or some combination of the two.

(iv) Whether the MA plan's proposed provider network meet Medicare time and distance standards for member access to health care providers including specialties.

(v) Other factors that CMS determines are relevant in setting a standard for an acceptable health care delivery network in a particular service area.

* * * * *

Subpart D—Quality Improvement

21. Section 422.152 is amended by—

A. Revising paragraphs (a)(1) and (a)(2).

B. Redesignating paragraph (b)(3)(ii) as paragraph (b)(3)(iii).

C. Adding new paragraph (b)(3)(ii).

D. Adding new paragraph (b)(5).

F. Redesignating paragraphs (e)(2)(ii) and (e)(2)(iii) as paragraphs (e)(2)(iii) and (e)(2)(iv), respectively.

H. Adding a new paragraph (e)(2)(ii).

The revisions and additions read as follows:

§ 422.152 Quality improvement program.

(a) * * *

(1) Have a chronic care improvement program that meets the requirements of paragraph (c) of this section concerning elements of a chronic care program and addresses populations identified by CMS based on a review of current quality performance;

(2) Conduct quality improvement projects that can be expected to have a favorable effect on health outcomes and enrollee satisfaction, meet the requirements of paragraph (d) of this section, and address areas identified by CMS; and

* * * * *

(b) * * *

(3) * * *

(ii) Collect, analyze, and report quality performance data identified by CMS that are of the same type as those under paragraph (b)(3)(i) of this section.

* * * * *

(5) All coordinated care contracts (including local and regional PPOs and contracts with exclusively SNP benefit packages, cost contracts under section 1876 of the Act, private fee-for-service contracts, and MSA contracts with 600 or more enrollees in July of the prior year) must contract with approved Medicare Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey vendors to conduct the Medicare CAHPS satisfaction survey of MA plan enrollees in accordance with CMS specifications, and submit the survey data to CMS.

* * * * *

(e) * * *

(2) * * *

(ii) Collect, analyze, and report quality performance data identified by CMS that are of the same type as those described under paragraph (e)(2)(i) of this section.

* * * * *

22. Section 422.153 is added to read as follows:

§ 422.153 Use of quality improvement organization review information.

CMS will acquire from quality improvement organizations (QIOs) as described in part 480 of this chapter quality review study information as defined in § 480.101(b) and subject to the requirements in § 480.140(g). CMS will acquire this information, as needed, and use it for the following limited functions:

(a) Enable beneficiaries to compare health coverage options and select among them.

(b) Evaluate plan performance.

(c) Ensure compliance with plan requirements under this part.

(d) Develop payment models.

(e) Other purposes related to MA plans as specified by CMS.

23. Section 422.156 is amended by revising paragraphs (b)(7) and (f) to read as follows:

§ 422.156 Compliance deemed on the basis of accreditation.

* * * * *

(b) * * *

(7) The requirements listed in § 423.165 (b)(1) through (3) for MA organizations that offer prescription drug benefit programs.

* * * * *

(f) *Authority.* Nothing in this subpart limits CMS' authority under subparts K and O of this part, including but not limited to, the ability to impose intermediate sanctions, civil money penalties, and terminate a contract with an MA organization.

Subpart F—Submission of Bids, Premiums, and Related Information and Plan Approval

24. Section 422.254 is amended by adding new paragraphs (a)(4) and (b)(5) to read as follows:

§ 422.254 Submission of bids.

* * * * *

(a) * * *

(4) *Substantial differences between bids.* An MA organization's bid submissions must reflect differences in benefit packages and plan costs that CMS determines to represent substantial

differences relative to a sponsor's other bid submissions.

* * * * *

(b) * * *

(5) *Actuarial valuation.* The bid must be prepared in accordance with CMS actuarial guidelines based on generally accepted actuarial principles.

(i) A qualified actuary must certify the plan's actuarial valuation (which may be prepared by others under his or her direction or review).

(ii) To be deemed a qualified actuary, the actuary must be a member of the American Academy of Actuaries.

(iii) Applicants may use qualified outside actuaries to prepare their bids.

* * * * *

25. Section 422.256 is amended by adding a new paragraph (b)(4) to read as follows:

§ 422.256 Review, negotiation, and approval of bids.

* * * * *

(b) * * *

(4) *Substantial differences between bids.*

(i) *General.* CMS approves a bid only if it finds that the benefit package and plan costs represented by that bid are substantially different from the MA organization's other bid submissions. In order to be considered "substantially different," each bid must be significantly different from other plans of its plan type with respect to premiums, benefits, or cost-sharing structure.

(ii) Transition period for MA organizations with new acquisitions. After a 2-year transition period, CMS approves a bid offered by an MA organization (or by a parent organization to that MA organization) that recently purchased (or otherwise acquired or merged with) another MA organization only if it finds that the benefit package and plan costs represented by that bid are substantially different, as provided under paragraph (b)(4)(i) of this section, from any benefit package and plan costs represented by another bid submitted by the same MA organization (or parent organization to that MA organization).

* * * * *

Subpart G—Payments to Medicare Advantage Organizations

26. Section 422.306 is amended by revising paragraph (a) to read as follows:

§ 422.306 Annual MA capitation rates.

* * * * *

(a) *Minimum percentage increase rate.* The annual capitation rate for each MA local area is equal to the minimum percentage increase rate, which is the

annual capitation rate for the area for the preceding year increased by the national per capita MA growth percentage (defined at § 422.308(a)) for the year, but not taking into account any adjustment under § 422.308(b) for a year before 2004.

* * * * *

27. A new § 422.311 is added to read as follows.

§ 422.311 RADV audit dispute and appeal processes.

(a) *Risk Adjustment Data Validation (RADV) audits.* In accordance with § 422.2 and § 422.310 *et seq.*, CMS annually conducts RADV audits to ensure risk adjusted payment integrity and accuracy.

(b) *RADV audit results.*

(1) MA organizations that undergo RADV audits will be issued an audit report post medical record review that describes the results of the RADV audit as follows:

(i) Detailed enrollee-level information relating to confirmed enrollee HCC discrepancies.

(ii) The contract-level RADV payment error estimate in absolute dollars.

(iii) The contract-level payment adjustment amount to be made in absolute dollars.

(iv) An approximate timeframe for the payment adjustment.

(v) An enrollee-level description of HCC-level discrepancies that will be eligible for dispute.

(vi) A description of the MA organization's RADV audit appeal rights.

(2) *Compliance date.* The compliance date for meeting RADV medical record submission requirements for the validation of risk adjustment data is the due date when MA organizations selected for RADV audit must submit medical records to CMS or its contractors.

(c) *RADV audit dispute and appeal processes.*

(1) *Attestation process.*

(i) MA organizations—

(A) May submit CMS-generated attestations from physician/practitioner(s) in order to dispute signature or credential-related RADV errors.

(B) That submit CMS-generated attestations must do so in accordance with the rules under this section.

(C) Are not obligated to submit attestations to CMS.

(ii) *RADV audit-related errors eligible for attestation process.* CMS will only accept an attestation to support a physician or outpatient medical records with missing or illegible signatures or missing or illegible credentials or both.

(iii) *RADV audit-related errors ineligible for attestation process.*

(A) Attestations from providers, for the purpose of resolving coding discrepancies or other medical record documentation, will not be permitted.

(B) The introduction of new HCCs for payment that were not previously identified by CMS for RADV audit will not be eligible for attestation.

(C) Inpatient provider-type medical records are not eligible for attestation.

(iv) *Manner and timing of a request for attestation.*

(A) At the time CMS notifies an MA organization that it has been selected for RADV audit, CMS provides the MA organization with the attestation forms and instructions regarding the submission of attestations.

(B) If an organization decides to submit attestations completed by physicians or other practitioners, the MA organization must submit the attestations to CMS at the same time that the MA organization is required to submit related medical records for RADV audit.

(v) *Attestation content.* An attestation must accompany and correspond to the medical record submitted for RADV audit and must meet the following requirements:

(A) Only CMS-generated attestations will be accepted by CMS.

(B) The CMS attestation form may not be altered unless otherwise instructed and agreed-upon in writing by CMS.

(C) Attestations must be completed and be signed and dated by the RADV-physician/practitioner whose medical record accompanies the attestation.

(D) Attestations must be based upon medical records that document face-to-face encounters between beneficiaries and RADV-eligible physicians/practitioners.

(vi) *Attestation review and determination procedures.*

(A) CMS reviews each submitted attestation to determine if it meets CMS requirements and is acceptable for use during the medical record review.

(B) CMS provides written notice of its determination(s) regarding submitted attestations to the MA organization at the time CMS issues its RADV audit report.

(vii) *Effect of CMS' attestation determination.* CMS' attestation determination is final and binding.

(2) *Documentation dispute process.*

An MA organization may choose to dispute CMS' operational processing of RADV medical records using a CMS-administered documentation dispute process.

(i) *RADV-related errors eligible for documentation dispute process.* The

documentation dispute process will apply only to the operational processing of those medical records selected for RADV audit. In order to be eligible for documentation dispute, medical records have to have been submitted to CMS by the CMS-established deadline.

(ii) RADV-related audit errors ineligible for documentation dispute process.

(A) Medical record coding discrepancies.

(B) MA organizations may not use the documentation dispute process to submit new medical records in place of previously-submitted medical records.

(C) MA organizations may not use the documentation dispute process to introduce new HCCs for payment that were not earlier identified by CMS for audit.

(D) MA organizations may not submit medical records for HCCs that were in error because the MA organization failed to meet the medical record submission deadline established by CMS.

(iii) *Manner and timing of a request for documentation dispute.*

(A) At the time CMS issues its RADV audit report to affected MA organizations, CMS notifies affected MA organizations of any RADV errors that are eligible for documentation dispute.

(B) MA organizations have 30 days from date of issuance of the RADV audit report to request documentation dispute.

(iv) *Documentation dispute review and notification procedures.*

(A) CMS reviews documentation submitted by MA organizations to determine whether it supports overturning errors listed in the MA organization's RADV audit report.

(B) CMS provides written notice of its determination(s) to the MA organization and notifies the MA organization of its aggregate determinations regarding overturning errors listed in the MA organization's RADV audit report and recalculating the MA organization's RADV payment error.

(v) *Effect of CMS documentation dispute determination.* CMS' documentation dispute determination is final and binding.

(3) *RADV payment error calculation appeal process.*

(i) MA organizations may appeal CMS' RADV payment error calculation.

(ii) RADV payment error-related issues ineligible for appeal.

(A) MA organizations may not appeal RADV medical record review-related errors.

(B) MA organizations may not appeal physician/practitioner signature or credential-related medical record review errors.

(C) MA organizations may not introduce new HCCs to CMS for payment consideration in the context of their RADV payment error calculation appeal.

(D) MA organizations may not appeal RADV errors that result from an MA organization's failure to submit a medical record.

(E) MA organizations may not appeal CMS' RADV payment error calculation methodology.

(iii) *Manner and timing of a request for appeal.*

(A) At the time CMS issues its RADV audit report, CMS notifies affected MA organizations in writing of their appeal rights around the RADV payment error calculation.

(B) MA organizations have 30 days from the date of this notice to submit a written request for reconsideration of its RADV payment error calculation.

(iv) *Burden of proof.* The MA organization bears the burden of proof in demonstrating that CMS failed to follow its stated RADV payment error calculation methodology.

(v) *Content of request.* The written request for reconsideration must specify the issues with which the MA organization disagrees and the reasons for the disagreements.

(A) Excluding evidence pertaining to issues described at § 422.311(c) (1) and (2), the written request for reconsideration may include additional documentary evidence the MA organization wishes CMS to consider.

(B) CMS does not accept reconsiderations for issues with the methodology applied in any part of the RADV audit.

(vi) *Conduct of written reconsideration.*

(A) In conducting the written reconsideration, CMS reviews all of the following information:

(1) The RADV payment error calculation.

(2) The evidence and findings upon which they were based.

(3) Any other written evidence submitted by the MA organization.

(B) CMS ensures that a third party—either within CMS or a CMS contractor—not otherwise involved in the RADV payment error calculation reviews the written request for reconsideration.

(C) The third party recalculates the payment error in accordance with CMS RADV payment calculation procedures described in CMS' RADV payment error calculation standard operating procedures.

(D) The third party described in paragraph (B) of this paragraph provides his or her determination to a CMS

reconsideration official not otherwise involved in the RADV payment error calculation to review the reconsideration determination.

(vii) *Decision of the CMS reconsideration official.* The CMS reconsideration official informs the MA organization and CMS in writing of the decision of the CMS reconsideration official.

(viii) *Effect of the CMS reconsideration official.* The written reconsideration decision is final and binding unless a request for a hearing is filed by CMS or the appellant MA organization in accordance with paragraph (c)(4) of this section.

(4) *Right to a hearing.* CMS or an MA organization dissatisfied with the written decision of the CMS reconsideration official is entitled to a hearing as provided in this section.

(i) *Manner and timing for request.* A request for a hearing must be made in writing and filed with CMS within 30 days of the date CMS and the MA organization receives CMS' written reconsideration decision.

(ii) *Content of request.* The written request for hearing must include a copy of the written decision of the CMS reconsideration official and must specify the findings or issues in the reconsideration decision with which either CMS or the MA organization disagrees and the reasons for the disagreement.

(iii) *Hearing procedures.*

(A) The hearing will be held on the record, unless the parties request, subject to the hearing officer's discretion, a live or telephonic hearing. The hearing officer may schedule a live or telephonic hearing on his/her own motion.

(B) The hearing is conducted by an official from the CMS' Office of Hearings (CMS Hearing Officer) who neither receives testimony nor accepts any new evidence that was not presented with the request for reconsideration. The CMS Hearing Officer is limited to the review of the record that was before CMS when CMS made its initial RADV payment error calculation determination and when the CMS reconsideration official issued the written reconsideration decision.

(C) The hearing officer has full power to make rules and establish procedures, consistent with the law, regulations, and CMS rulings. These powers include the authority to dismiss the appeal with prejudice or take any other action which the hearing officer considers appropriate for failure to comply with such rules and procedures.

(iv) *Decision of the CMS Hearing Officer.* The CMS Hearing Officer

decides whether the reconsideration official's decision was correct, and sends a written decision to CMS and the MA organization, explaining the basis for the decision.

(v) *Effect of the Hearing Officer's decision.* The Hearing Officer's decision is final and binding, unless the decision is reversed or modified by the Administrator in accordance with paragraph (c)(5) of this section.

(5) *Review by the CMS Administrator.* (i) At his or her discretion, the CMS Administrator can choose to either review or not review a case.

(ii) CMS or an MA organization that has received a Hearing Officer decision upholding or overturning a CMS initial or reconsideration-level RADV payment error calculation determination may request review by the Administrator within 30 days of receipt of the Hearing Officer's decision.

(iii) If the CMS Administrator chooses to review the case, the CMS Administrator reviews the Hearing Officer's decision, any written documents submitted by CMS or the MA organization to the Hearing Officer, as well as any other information included in the record of the Hearing Officer's decision and determines whether to uphold, reverse, or modify the Hearing Officer's decision.

(iv) The Administrator's determination is final and binding.

Subpart K—Contracts With Medicare Advantage Organizations

28. Section 422.501 is amended by—
A. Redesignating paragraphs (b) through (e) as paragraphs (c) through (f), respectively.

B. Adding a new paragraph (b).

C. Revising newly redesignated paragraph (c)(1) introductory text and paragraph (c)(2).

The addition and revisions read as follows:

§ 422.501 Application requirements.

* * * * *

(b) *Completion of a notice of intent to apply.*

(1) An organization submitting an application under this section for a particular contract year must first submit a completed Notice of Intent to Apply by the date established by CMS. CMS will not accept applications from organizations that do not first submit a timely Notice of Intent to Apply.

(2) Submitting a Notice of Intent to Apply does not bind that organization to submit an application for the applicable contract year.

(c) * * *

(1) In order to obtain a determination on whether it meets the requirements to

become an MA organization and is qualified to provide a particular type of MA plan, an entity, or an individual authorized to act for the entity (the applicant) must fully complete all parts of a certified application, in the form and manner required by CMS, including the following:

* * * * *

(2) The authorized individual must thoroughly describe how the entity and MA plan meet, or will meet, all the requirements described in this part.

* * * * *

29. Section 422.502 is amended by—
A. Revising paragraphs (a)(1), (a)(2), and (b).

B. Adding a new paragraph (c)(2)(iii).

C. Revising paragraph (c)(3)(iii).

D. Removing paragraph (d).

The revisions read as follows:

§ 422.502 Evaluation and determination procedures.

(a) * * *

(1) With the exception of evaluations conducted under paragraph (b) of this section, CMS evaluates an application for an MA contract solely on the basis of information contained in the application itself and any additional information that CMS obtains through other means such as on-site visits.

(2) After evaluating all relevant information, CMS determines whether the applicant's application meets all the requirements described in this part.

(b) *Use of information from a current or prior contract.* If an MA organization fails during the 14 months preceding the deadline established by CMS for the submission of contract qualification applications to comply with the requirements of the Part C program under any current or prior contract with CMS under title XVIII of the Act or fails to complete a corrective action plan during the 14 months preceding the deadline established by CMS for the submission of contract qualification applications, CMS may deny an application based on the applicant's failure to comply with the requirements of the Part C program under any current or prior contract with CMS even if the applicant currently meets all of the requirements of this part.

(c) * * *

(2) * * *

(iii) If CMS does not receive a revised application within 10 days from the date of the notice, or if after timely submission of a revised application, CMS still finds the applicant does not appear qualified to contract as an MA organization or has not provided enough information to allow CMS to evaluate the application, CMS will deny the application.

(3) * * *

(iii) The applicant's right to request a hearing in accordance with the procedures specified in subpart N of this part.

30. Section 422.503 is amended by—

A. Revising paragraph (b)(4)(vi).

B. Adding new paragraph (b)(7).

The revisions and addition read as follows:

§ 422.503 General provisions.

* * * * *

(b) * * *

(4) * * *

(vi) Adopt and implement an effective compliance program, which must include measures that prevent, detect, and correct non-compliance with CMS' program requirements as well as measures that prevent, detect, and correct fraud, waste, and abuse. The compliance program must, at a minimum, include the following core requirements:

(A) Written policies, procedures, and standards of conduct that—

(1) Articulate the organization's commitment to comply with all applicable Federal and State standards;

(2) Describe compliance expectations as embodied in the standards of conduct,

(3) Implement the operation of the compliance program;

(4) Provide guidance to employees and others on dealing with potential compliance issues;

(5) Identify how to communicate compliance issues to appropriate compliance personnel;

(6) Describe how potential compliance issues are investigated and resolved by the organization; and

(7) Include a policy of non-intimidation and non-retaliation for good faith participation in the compliance program, including but not limited to reporting potential issues, investigating issues, conducting self-evaluations, audits and remedial actions, and reporting to appropriate officials.

(B) The designation of a compliance officer and a compliance committee who report directly to the organization's chief executive or other senior administrator.

(1) The compliance officer, vested with the day-to-day operations of the compliance program, must be an employee of the MA organization.

(2) The compliance officer and the compliance committee must periodically report directly to the governing body of the MA organization on the activities and status of the compliance program, including issues identified, investigated, and resolved by the compliance program.

(3) The governing body of the MA organization must be knowledgeable about the content and operation of the compliance program and must exercise reasonable oversight with respect to the implementation and effectiveness of the compliance programs.

(C)(1) Each MA organization must establish and implement effective training and education between the compliance officer and organization employees, the MA organization's chief executive or other senior administrator, managers and governing body members, and the MA organization's first tier, downstream, and related entities. Such training and education must occur at a minimum annually and must be made a part of the orientation for a new employee, new first tier, downstream and related entities, and new appointment to a chief executive, manager, or governing body member.

(2) First tier, downstream, and related entities who have met the fraud, waste, and abuse certification requirements through enrollment into the Medicare program are deemed to have met the training and educational requirements for fraud, waste, and abuse.

(D) Establishment and implementation of effective lines of communication, ensuring confidentiality, between the compliance officer, members of the compliance committee, the MA organization's employees, managers and governing body, and the MA organization's first tier, downstream, and related entities. Such lines of communication must be accessible to all and allow compliance issues to be reported including a method for anonymous and confidential good faith reporting of potential compliance issues as they are identified.

(E) Well-publicized disciplinary standards through the implementation of procedures which encourage good faith participation in the compliance program by all affected individuals. These standards must include policies that:

(1) Articulate expectations for reporting compliance issues and assist in their resolution,

(2) Identify noncompliance or unethical behavior; and

(3) Provide for timely, consistent, and effective enforcement of the standards when noncompliance or unethical behavior is determined.

(F) Establishment and implementation of an effective system for routine monitoring and identification of compliance risks. The system should include internal monitoring and audits and, as appropriate, external audits, to evaluate the MA organization, including first tier entities', compliance with CMS

requirements and the overall effectiveness of the compliance program.

(G) Establishment and implementation of procedures and a system for promptly responding to compliance issues as they are raised, investigating potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence, and ensure ongoing compliance with CMS requirements.

* * * * *

(7) Not have terminated a contract by mutual consent under which, as a condition of the consent, the MA organization agreed that it was not eligible to apply for new contracts or service area expansions for a period of 2 years per § 422.508(c) of this subpart.

* * * * *

31. Section 422.504 is amended by—
A. Redesignating paragraph (e)(1)(ii) and (e)(1)(iii) as paragraph (e)(1)(iii) and (e)(1)(iv), respectively.

B. Adding a new paragraph (e)(1)(ii).
C. Revising newly redesignated paragraph (e)(1)(iii).

D. Revising paragraph (i)(2)(i).
E. Add a new paragraph (m).

The additions and revisions read as follows:

§ 422.504 Contract provisions.

* * * * *

(e) * * *
(1) * * *

(ii) Compliance with CMS requirements for maintaining the privacy and security of personal health information and other personally identifiable information of Medicare enrollees;

(iii) The facilities of the MA organization to include computer and other electronic systems; and

* * * * *

(i) * * *
(2) * * *

(i) HHS, the Comptroller General, or their designees have the right to audit, evaluate, and inspect any books, contracts, computer or other electronic systems, including medical records and documentation of the first tier, downstream, and related to CMS' contract with the MA organization.

* * * * *

(m)(1) CMS may determine that an MA organization is out of compliance with Part C when the organization fails to meet performance standards articulated in the Part C statutes, regulations, or guidance.

(2) If CMS has not already articulated a measure for determining

noncompliance, CMS may determine that a MA organization is out of compliance when its performance represents an outlier relative to the performance of other MA organizations.

- 32. Section 422.506 is amended by—
A. Revising paragraph (a)(2)(ii).
B. Removing paragraph (a)(2)(iii).
C. Revising paragraph (a)(3)(i).
D. Adding a new paragraph (b)(1)(iv).
E. Revising paragraph (b)(2)(ii).
F. Removing paragraph (b)(2)(iii).
G. Revising paragraph (b)(3).

The revisions and addition read as follows:

§ 422.506 Nonrenewal of contract.

(a) * * *
(2) * * *

(ii) Each Medicare enrollee by mail at least 90 calendar days before the date on which the nonrenewal is effective. The MA organization must also provide information about alternative enrollment options by doing one or more of the following:

(A) Provide a CMS approved written description of alternative MA plan options available for obtaining qualified Medicare services within the beneficiaries' region.

(B) Place outbound calls to all affected enrollees to ensure beneficiaries know who to contact to learn about their enrollment options.

(3) * * *

(i) The MA organization notifies its Medicare enrollees in accordance with paragraph (a)(2)(ii) of this section; and

(b) * * *
(1) * * *

(iv) The contract must be nonrenewed as to an individual MA plan if that plan does not have a sufficient number of enrollees to establish that it is a viable independent plan option.

(2) * * *

(ii) To each of the MA organization's Medicare enrollees by mail at least 90 calendar days before the date on which the nonrenewal is effective, or at the conclusion of the appeals process if applicable.

(3) *Opportunity to develop and implement a corrective action plan.*

(i) Before providing a notice of intent of nonrenewal of the contract, CMS will provide the MA organization with a notice specifying the deficiencies and reasonable opportunity to develop and implement a corrective action plan to correct the deficiencies that form the basis for the determination to non-renew the contract.

(ii) CMS affords the MA organization with at least 30 calendar days in which to develop and implement a corrective action plan to correct the deficiencies

that formed the basis for the determination to non-renew the contract.

(iii) The MA organization is solely responsible for the identification, development, and implementation of its corrective action plan and for demonstrating to CMS that the underlying deficiencies have been corrected within the time period specified by CMS in the notice requesting corrective action.

* * * * *

33. Section 422.508 is amended by adding paragraph (c) to read as follows:

§ 422.508 Modification or termination of contract by mutual consent.

* * * * *

(c) *Agreement to limit new MA applications.* As a condition of the consent to a mutual termination CMS will require, as a provision of the termination agreement language prohibiting the MA organization from applying for new contracts or service area expansions for a period of 2 years, absent circumstances warranting special consideration.

34. Section 422.510 is amended by revising paragraphs (a), (b) introductory text, (b)(2)(i), (b)(2)(ii), and (c) to read as follows:

§ 422.510 Termination of contract by CMS.

(a) *Termination by CMS.*

(1) CMS may at any time terminate a contract if CMS determines that the MA organization meets any of the following:

(i) Has failed substantially to carry out the contract.

(ii) Is carrying out the contract in a manner that is inconsistent with the efficient and effective administration of this part.

(iii) No longer substantially meets the applicable conditions of this part.

(2) CMS may determine, in

accordance with paragraph (a)(1) of this section, that a basis exists to terminate an MA organization's contract if—

(i) The MA organization fails to comply with any of the regulatory requirements contained in this part or part 423 of this chapter or both;

(ii) The MA organization fails to meet CMS performance requirements in carrying out the regulatory requirements contained in this part or part 423 of this chapter or both including, but not limited to, when CMS determines that an analysis of data related to the organization's performance indicates it is an outlier relative to that of other organizations; or

(iii) There is credible evidence to show that the MA organization has committed or participated in false, fraudulent, or abusive activities

affecting the Medicare, Medicaid, or other State or Federal health care programs, including submission of false or fraudulent data.

(b) *Notice.* If CMS decides to terminate a contract it gives notice of the termination as follows:

(1) * * *

(2) *Expedited termination of contract by CMS.* (i) If CMS determines that a delay in termination, resulting from compliance with the procedures provided in this part prior to termination, would pose an imminent and serious risk to the health of the individuals enrolled with the MA organization, the effective date of termination will be specified, in writing, by CMS.

(ii) If a termination is effective in the middle of a month, CMS has the right to recover the prorated share of the capitation payments made to the MA organization covering the period of the month following the contract termination.

* * * * *

(c) Opportunity to develop and implement a corrective action plan.

(1) *General.* (i) Before providing a notice of intent to terminate the contract, CMS will provide the MA organization with a notice specifying the deficiencies and reasonable opportunity to develop and implement a corrective action plan to correct the deficiencies that form the basis for the determination to terminate the contract.

(ii) CMS affords the MA organization with at least 30 calendar days in which to develop and implement a corrective action plan to correct the deficiencies that formed the basis for the determination to terminate the contract.

(iii) The MA organization is solely responsible for the identification, development, and implementation of its corrective action plan and for demonstrating to CMS that the underlying deficiencies have been corrected within the time period specified by CMS in the notice requesting corrective action.

(2) *Exceptions.* If CMS determines that a delay in termination, resulting from compliance with the procedures provided in this part prior to termination, would pose an imminent and serious risk to the health of the individuals enrolled with the MA organization, the MA organization will not be provided with an opportunity to develop and implement a corrective action plan prior to termination.

* * * * *

35. Section 422.516 is amended by—
A. Revising the section heading.
B. Adding a new paragraph (g).

The revision and addition to read as follows:

§ 422.516 Validation of Part C reporting requirements.

* * * * *

(g) *Data validation.* Each Part C sponsor must subject information collected under paragraph (a) of this section to a yearly independent audit to determine their reliability, validity, completeness, and comparability in accordance with specifications developed by CMS.

Subpart M—Grievances, Organization Determinations, and Appeals

36. Section 422.561 is amended by revising the definition of “Representative” to read as follows:

§ 422.561 Definitions.

* * * * *

Representative means an individual appointed by an enrollee or other party, or authorized under State or other applicable law, to act on behalf of an enrollee or other party involved in the grievance or appeal. Unless otherwise stated in this subpart, the representative will have all the rights and responsibilities of an enrollee or party in filing a grievance, and in obtaining an organization determination or in dealing with any of the levels of the appeals process, subject to the applicable rules described in part 405 of this chapter.

37. Section 422.566 is amended by revising paragraph (b)(4) to read as follows:

§ 422.566 Organization determinations.

* * * * *

(b) * * *

(4) Discontinuation or reduction of a service or an authorized course of treatment.

* * * * *

38. Section 422.568 is amended by—
A. Redesignating paragraphs (a) through (f) as paragraphs (b) through (g), respectively.

B. Adding a new paragraph (a).

C. Revising newly redesignated paragraph (e).

The addition and revision read as follows:

§ 422.568 Standard timeframes and notice requirements for organization determinations.

(a) *Method and place for filing a request.* An enrollee must ask for a standard organization determination by making a request with the MA organization or, if applicable, to the entity responsible for making the determination (as directed by the MA organization), in accordance with the following:

(1) The request may be made orally or in writing, except as provided in paragraph (a)(2) of this section.

(2) Requests for payment must be made in writing (unless the MA organization or entity responsible for making the determination has implemented a voluntary policy of accepting oral payment requests).

* * * * *

(e) *Written notice for MA organization denials.*

(1) If an MA organization decides to deny a service or payment in whole or in part, or discontinue or reduce the level of care for an authorized course of treatment, the organization must give the enrollee written notice of the determination.

(2) If an enrollee requests an MA organization to provide an explanation of a practitioner’s denial of an item or service, in whole or in part, the MA organization must give the enrollee a written notice.

* * * * *

39. Section 422.574 is amended by revising paragraph (a) to read as follows:

§ 422.574 Parties to the organization determination.

* * * * *

(a) The enrollee (including his or her representative);

* * * * *

40. Section 422.622 is amended by revising paragraph (f)(3) to read as follows:

§ 422.622 Requesting immediate QIO review of the decision to discharge from the inpatient hospital.

* * * * *

(f) * * *

(3) If the QIO determines that the enrollee still requires inpatient hospital care, the hospital must provide the enrollee with a notice consistent with § 422.620(c) of this subpart when the hospital or MA organization once again determines that the enrollee no longer requires inpatient hospital care.

* * * * *

41. Section 422.624 is amended by revising paragraph (c)(1) to read as follows:

§ 422.624 Notifying enrollees of termination of provider services.

* * * * *

(c) * * *

(1) The enrollee (or the enrollee’s representative) has signed and dated the notice to indicate that he or she has received the notice and can comprehend its contents; and

* * * * *

42. Section 422.626 is amended by—

A. Redesignating paragraph (f) as paragraph (g).

B. Redesignating paragraph (e)(5) as paragraph (f) and revising the newly redesignated paragraph (f).

The revisions read as follows:

§ 422.626 Fast-track appeals of service terminations to independent review entities (IREs).

* * * * *

(f) *Responsibilities of the provider.* If an IRE reverses an MA organization's termination decision, the provider must provide the enrollee with a new notice consistent with § 422.624(b) of this subpart.

* * * * *

Subpart N—Medicare Contract Determinations and Appeals

43. Section 422.644 is amended by revising paragraph (c) to read as follows:

§ 422.644 Notice of contract determination.

* * * * *

(c) *CMS-initiated terminations.*

(1) *General rule.* CMS mails notice to the MA organization 90 calendar days before the anticipated effective date of the termination.

(2) *Exception.* For terminations where CMS determines that a delay in termination, resulting from compliance with the procedures provided in this part prior to termination, would pose an imminent and serious risk to the health of the individuals enrolled with the MA organization, CMS notifies the MA organization of the date that it will terminate the MA organization's contract.

* * * * *

44. Section § 422.660 is revised to read as follows:

§ 422.660 Right to a hearing, burden of proof, standard of proof, and standards of review.

(a) *Right to a hearing.* The following parties are entitled to a hearing:

(1) A contract applicant that has been determined to be unqualified to enter into a contract with CMS under Part C of Title XVIII of the Act in accordance with § 422.501 and § 422.502.

(2) An MA organization whose contract has been terminated under § 422.510 of this part.

(3) An MA organization whose contract has not been renewed under § 422.506 of this part.

(4) An MA organization who has had an intermediate sanction imposed in accordance with § 422.752(a) through (b) of this part.

(b) *Burden of proof, standard of proof, and standards of review at a hearing.*

(1) During a hearing to review a contract determination as described at

§ 422.641(a) of this subpart, the applicant has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of § 422.501 and § 422.502 of this part.

(2) During a hearing to review a contract determination as described at § 422.641(b) of this subpart, the MA organization has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of § 422.506 of this part.

(3) During a hearing to review a contract determination as described at § 422.641(c) of this subpart, the MA organization has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of § 422.510 of this part.

(4) During a hearing to review the imposition of an intermediate sanction as described at § 422.750 of this part, the MA organization has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of § 422.752 of this part.

(c) *Timing of favorable decisions.* Notice of any decision favorable to the MA organization appealing a determination that it is not qualified to enter into a contract with CMS must be issued by September 1 for the contract in question to be effective on January 1 of the following year.

45. Section 422.662 is amended by revising paragraphs (a) and (b) to read as follows:

§ 422.662 Request for hearing.

(a) *Method and place for filing a request.* (1) A request for a hearing must be made in writing and filed by an authorized official of the contract applicant or MA organization that was the party to the determination under the appeal.

(2) The request for the hearing must be filed in accordance with the requirements specified in the notice.

(b) *Time for filing a request.* A request for a hearing must be filed within 15 calendar days after the receipt of the notice of the contract determination or intermediate sanction.

* * * * *

46. Section 422.664 is amended by revising paragraph (b)(2) to read as follows:

§ 422.664 Postponement of effective date of a contract determination when a request for a hearing is filed timely.

* * * * *

(b) * * *

(2) If CMS determines that a delay in termination, resulting from compliance

with the procedures provided in this part prior to termination, would pose an imminent and serious risk to the health of individuals enrolled with the MA organization, the date of termination will not be postponed if the MA organization requests a hearing.

47. Section 422.670 is revised to read as follows:

§ 422.670 Time and place of hearing.

(a) The hearing officer—

(1) Fixes a time and place for the hearing, which is not to exceed 30 calendar days after the receipt of the request for the hearing; and

(2) Sends written notice to the parties that informs the parties of the general and specific issues to be resolved, the burden of proof, and information about the hearing procedure.

(b)(1) The hearing officer may, on his or her own motion, change the time and place of the hearing.

(2) The hearing officer may adjourn or postpone the hearing.

(c)(1) The MA organization or CMS may request an extension by filing a written request no later than 5 calendar days prior to the scheduled hearing.

(2) When either the MA organization or CMS requests an extension, the hearing officer will provide a one-time 15 calendar day extension.

(3) Additional extensions may be granted at the discretion of the hearing officer.

48. Section 422.676 is amended by revising paragraph (d) to read as follows:

§ 422.676 Conduct of hearing.

* * * * *

(d) The MA organization bears the burden of going forward and must first present evidence and argument before CMS presents its evidence and argument.

49. Section 422.682 is revised to read as follows:

§ 422.682 Witness lists and documents.

Witness lists and documents must be identified and exchanged at least 5 calendar days before the scheduled hearing.

50. Section 422.692 is amended by revising paragraphs (a) and (c) to read as follows:

§ 422.692 Review by the Administrator.

(a) *Request for review by Administrator.* CMS or an MA organization that has received a hearing decision may request a review by the Administrator within 15 calendar days after receipt of the hearing decision as provided under § 422.690(b). Both the MA organization and CMS may provide

written arguments to the Administrator for review.

* * * * *

(c) *Notification of Administrator determination.* The Administrator notifies both parties of his or her determination regarding review of the hearing decision within 30 calendar days after receipt of request for review. If the Administrator declines to review the hearing decision or the Administrator does not make a determination regarding review within 30 calendar days, the decision of the hearing officer is final.

* * * * *

51. Section 422.696 is amended by revising the section heading and paragraph heading for paragraph (a) to read as follows:

§ 422.696 Reopening of a contract determination or decision of a hearing officer or the Administrator.

(a) *Contract determination.* * * *

* * * * *

Subpart O—Intermediate Sanctions

52. Section 422.750 is amended by revising paragraph (a) to read as follows:

§ 422.750 Types of intermediate sanctions and civil money penalties.

(a) The following intermediate sanctions may be imposed and will continue in effect until CMS is satisfied that the deficiencies that are the basis for the sanction determination have been corrected and are not likely to recur:

(1) Suspension of the MA organization's enrollment of Medicare beneficiaries.

(2) Suspension of payment to the MA organization for Medicare beneficiaries enrolled after the date CMS notifies the organization of the intermediate sanction.

(3) Suspension of all marketing activities to Medicare beneficiaries by an MA organization.

* * * * *

53. Section 422.752 is amended by—

A. Revising paragraphs (a) introductory text, (a)(1), (a)(3), and (a)(4).

B. In paragraph (c)(1), removing the cross-reference “422.510(a)(4)” and adding the cross-reference “§ 422.510(a)(2)(iii) of this part” in its place.

C. In paragraph (c)(2)(iii), removing the phrase “pursuant to 422.510(a)(4)” and adding the phrase “under § 422.510(a)(2)(iii) of this part” in its place.

The revisions read as follows:

§ 422.752 Basis for imposing intermediate sanctions and civil money penalties.

(a) *All intermediate sanctions.* For the violations listed in this paragraph, CMS may impose one or more of the sanctions specified in § 422.750(a) of this subpart on any MA organization with a contract. The MA organization may also be subject to other remedies authorized under law.

(1) Fails substantially to provide medically necessary items and services that are required (under law or under the contract) to be provided to an individual covered under the contract, if the failure has adversely affected (or has the substantial likelihood of adversely affecting) the individual.

* * * * *

(3) Acts to expel or refuses to re-enroll a beneficiary in violation of the provisions of this part.

(4) Engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by this part) by eligible individuals with the organization whose medical condition or history indicates a need for substantial future medical services.

* * * * *

54. Section 422.756 amended by—

A. Revising paragraph (b).

B. Removing paragraph (c).

C. Redesignating paragraphs (d) through (f) as paragraphs (c) through (e), respectively.

D. Revising the newly redesignated paragraphs (c)(1) and (c)(3).

The revisions read as follows:

§ 422.756 Procedures for imposing intermediate sanctions and civil money penalties.

* * * * *

(b) *Hearing.* (1) The MA organization may request a hearing before a CMS hearing officer.

(2) A written request must be received by the designated CMS office within 15 calendar days after the receipt of the notice.

(3) A request for a hearing under § 422.660 does not delay the date specified by CMS when the sanction becomes effective.

(4) The MA organization must follow the right to a hearing procedure as specified at § 422.660 through § 422.684.

(c) *Effective date and duration of sanction.* (1) *Effective date.* The effective date of the sanction is the date specified by CMS in the notice.

* * * * *

(3) *Duration of sanction.* The sanction remains in effect until CMS is satisfied that the deficiencies that are the basis for the sanction determination have

been corrected and are not likely to recur.

(i) CMS may require that the MA organization hire an independent auditor to provide CMS with additional information to determine if the deficiencies that are the basis for the sanction determination have been corrected and are not likely to recur. The independent auditor must work in accordance with CMS specifications and must be willing to attest that a complete and full independent review has been performed.

(ii) In instances where marketing or enrollment or both intermediate sanctions have been imposed, CMS may require an MA organization to market or to accept enrollments or both for a limited period of time in order to assist CMS in making a determination as to whether the deficiencies that were the bases for the intermediate sanctions have been corrected and are not likely to recur.

(A) If, following this time period, CMS determines the deficiencies have not been corrected or are likely to recur, the intermediate sanctions will remain in effect until such time that CMS is assured the deficiencies have been corrected and are not likely to recur.

(B) The MA organization does not have a right to a hearing under § 422.660(a)(4) of this part to challenge CMS' determination to keep the intermediate sanctions in effect.

* * * * *

Subpart V—Medicare Advantage Marketing Requirements

55. Section 422.2260 is amended by revising paragraph (5)(vii) of the definition of “Marketing materials” to read as follows:

§ 422.2260 Definitions concerning marketing materials.

* * * * *

(5) * * *

(vii) *Membership activities—Current enrollee communication materials.* Current enrollee communication materials include any informational materials that are—

(A) Targeted to current enrollees; and
(B) Customized or limited to a subset of enrollees or apply to a specific situation; or

(C) Cover claims processing or other operational issues.

56. Section 422.2262 is amended by—

A. Revising paragraphs (a)(1) and (b).

B. Adding new paragraphs (c) and (d).

The revisions and additions read as follows:

§ 422.2262 Required use of standardized model materials.

(a) * * *

(1) Except as provided in paragraph (b) of this section, an MA organization may not distribute any marketing materials (as defined in § 422.2260 of this subpart), or election forms, or make such materials or forms available to individuals eligible to elect an MA organization unless—

(i) At least 45 days (or 10 days if using certain types of marketing materials that use, without modification, proposed model language and format, including standardized language and formatting, as specified by CMS) before the date of distribution the MA organization has submitted the material or form to CMS for review under the guidelines in § 422.2264 of this subpart; and

(ii) CMS does not disapprove the distribution of new material or form.

* * * * *

(b) *File and use.* The MA organization may distribute certain types of marketing material, designated by CMS, 5 days following their submission to CMS if the MA organization certifies that in the case of these marketing materials, it followed all applicable marketing guidelines and, when applicable, used model language specified by CMS without modification.

(c) *Standardized model marketing materials.* When specified by CMS, organizations must use standardized formats and language in model materials.

(d) *Current enrollee communication materials.* Current enrollee communication materials may be reviewed by CMS, which may upon review determine that such materials must be modified, or may no longer be used.

PART 423—MEDICARE PROGRAM; MEDICARE PRESCRIPTION DRUG PROGRAM

57. The authority citation for part 423 continues to read as follows:

Authority: Secs. 1102, 1860D–1 through 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395w–101 through 1395w–152, and 1395hh).

Subpart B—Eligibility and Enrollment

58. Section 423.34 is revised to read as follows:

§ 423.34 Enrollment of low-income subsidy eligible individuals.

(a) *General rule.* CMS must ensure the enrollment into Part D plans of low-income subsidy eligible individuals who fail to enroll in a Part D plan.

(b) *Definitions.*

Full-benefit dual-eligible individual. For purposes of this section, a full-benefit dual eligible individual means an individual who is—

(1) Determined eligible by the State for—

(i) Medical assistance for full-benefits under Title XIX of the Act for the month under any eligibility category covered under the State plan or comprehensive benefits under a demonstration under section 1115 of the Act; or

(ii) Medical assistance under section 1902(a)(10)(C) of the Act (medically needy) or section 1902(f) of the Act (States that use more restrictive eligibility criteria than are used by the SSI program) for any month if the individual was eligible for medical assistance in any part of the month.

(2) Eligible for Part D in accordance with § 423.30(a) of this subpart.

Low-income subsidy-eligible individual. For purposes of this section, a low-income subsidy eligible individual means an individual who meets the definition of full subsidy eligible (including full benefit dual eligible individuals) or other subsidy eligible in § 423.772 of this part.

(c) *Reassigning low-income subsidy-eligible individuals.* Notwithstanding § 423.32(e) of this subpart, during the annual coordinated election period, CMS may reassign certain low-income subsidy-eligible individuals in another PDP if CMS determines that the further enrollment is warranted.

(d) *Enrollment rules.*

(1) *General rule.* Except for low-income subsidy eligible individuals who are qualifying covered retirees with a group health plan sponsor as specified in paragraph (d)(3) of this section, CMS enrolls those individuals who fail to enroll in a Part D plan into a PDP offering basic prescription drug coverage in the area where the beneficiary resides that has a monthly beneficiary premium amount that does not exceed the low-income subsidy amount (as defined in § 423.780(b) of this part). In the event that there is more than one PDP in an area with a monthly beneficiary premium at or below the low-income premium subsidy amount, individuals are enrolled in such PDPs on a random basis.

(2) *Individuals enrolled in an MSA plan or one of the following that does not offer a Part D benefit.* Low-income subsidy eligible individuals enrolled in an MA private fee-for-service plan or cost-based HMO or CMP that does not offer qualified prescription drug coverage or an MSA plan and who fail to enroll in a Part D plan must be enrolled into a PDP plan as described in paragraph (d)(1) of this section.

(3) *Exception for individuals who are qualifying covered retirees.*

(i) Full benefit dual eligible individuals who are qualifying covered retirees as defined in § 423.882 of this part, and for whom CMS has approved the group health plan sponsor to receive the retirement drug subsidy described in subpart R of this part, also are automatically enrolled in a Part D plan, consistent with this paragraph, unless they elect to decline that enrollment.

(ii) Before effectuating such an enrollment, CMS provides notice to such individuals of their choices and advises them to discuss the potential impact of Medicare Part D coverage on their group health plan coverage. The notice informs individuals that they will be deemed to have declined to enroll in Part D unless they affirmatively enroll in a Part D plan or contact CMS and confirm that they wish to be auto-enrolled in a PDP. Individuals who elect not to be auto-enrolled, may enroll in Medicare Part D at a later time if they choose to do so.

(iii) All other low-income subsidy eligible beneficiaries who are qualified covered retirees are not enrolled by CMS into PDPs.

(e) *Declining enrollment and disenrollment.* Nothing in this section prevents a low-income subsidy eligible individual from—

(1) Affirmatively declining enrollment in Part D; or

(2) Disenrolling from the Part D plan in which the individual is enrolled and electing to enroll in another Part D plan during the special enrollment period provided under § 423.38.

(f) *Effective date of enrollment for full-benefit dual eligible individuals.* Enrollment of full-benefit dual eligible individuals under this section must be effective as follows:

(1) January 1, 2006 for individuals who are full-benefit dual-eligible individuals as of December 31, 2005.

(2) The first day of the month the individual is eligible for Part D under § 423.30(a)(1) for individuals who are Medicaid eligible and subsequently become newly eligible for Part D under § 423.30(a)(1) on or after January 1, 2006.

(3) For individuals who are eligible for Part D under § 423.30(a)(1) of this subpart and subsequently become newly eligible for Medicaid on or after January 1, 2006, enrollment is effective with the first day of the month when the individuals become eligible for both Medicaid and Part D.

(g) *Effective date of enrollment for non-full-benefit dual-eligible individuals who are low-income subsidy-eligible individuals.* The

effective date for non-full-benefit dual-eligible individuals who are low-income subsidy-eligible individuals is no later than the first day of the second month after CMS determines that they meet the criteria for enrollment under this section.

59. Section 423.38 is amended by revising paragraph (c)(4) to read as follows:

§ 423.38 Enrollment periods.

* * * * *

(c) * * *

(4) The individual is a full-subsidy eligible individual or other subsidy-eligible individual as defined in § 423.772 of this part.

* * * * *

60. Section 423.44 is amended by—

A. Redesignating paragraphs (d)(1)(iii) and (d)(1)(iv) as paragraphs (d)(1)(iv) and (d)(1)(v), respectively.

B. Adding a new paragraph (d)(1)(iii).

C. Redesignating the introductory text of paragraph (d)(5) as paragraph (d)(5)(i).

D. Adding new paragraph (d)(5)(ii).

The revisions and additions read as follows:

§ 423.44 Involuntary disenrollment by the PDP.

* * * * *

(d) * * *

(1) * * *

(iii) The PDP sponsor provides the individual with a grace period, that is, an opportunity to pay past due premiums in full. The grace period must—

(A) Be at least 2 months; and

(B) Begin on the first day of the month for which the premium is unpaid.

* * * * *

(5) * * *

(ii) *Special rule.* If the individual has not moved from the PDP service area, but has been absent from the service area for more than 12 consecutive months, the PDP sponsor must disenroll the individual from the plan effective on the first day of the 13th month after the individual left the service area.

* * * * *

Subpart C—Benefits and Beneficiary Protections

61. Section 423.100 is amended by adding the definitions of “Drug category or class,” “Major or life threatening clinical consequences,” “Multiple drugs,” “Restricted access,” and “Significant need for access to multiple drugs” to read as follows:

§ 423.100 Definitions.

* * * * *

Drug category or class means, for the purpose of § 423.120(b)(2)(v) of the subpart, the identification of a drug grouping that is reasonable to identify the applicable drug products.

* * * * *

Major or life threatening clinical consequences means consequences in which serious clinical events may arise as a result of not taking a drug that can lead to patient hospitalization, or a persistent or significant disability or incapacity, or that can result in death.

Multiple drugs mean two or more Part D drugs.

* * * * *

Restricted access means, for the purposes of § 423.120(b)(2)(v)(A) of this subpart, an enrollee who but for § 423.120(b)(2)(v) of this subpart urgently requires a Part D drug but is waiting for an expedited redetermination by a Part D plan or an CMS independent review entity with respect to coverage of that drug.

* * * * *

Significant need for access to multiple drugs means instances in which —

(1) There is a need for simultaneous use of drugs within a drug grouping because such drugs work in combination with each other; or

(2) There is a strong likelihood of sequential use of drugs within a class or category within a short period of time due to the unique effects the drugs have on various individuals.

* * * * *

62. Section 423.104 is amended by—

A. Revising paragraph (b).

B. Adding a new paragraph (d)(2)(iii).

The revision and addition read as follows:

§ 423.104 Requirements related to qualified prescription drug coverage.

* * * * *

(b) *Availability of prescription drug plan.* A PDP sponsor offering a prescription drug plan must offer the plan—

(1) To all Part D eligible beneficiaries residing in the plan’s service area; and

(2) At a uniform premium, with uniform benefits and level of cost-sharing throughout the plan’s service.

* * * * *

(d) * * *

(2) * * *

(iii) Tiered cost sharing under paragraph (d)(2)(ii) of this section may not exceed levels annually determined by CMS to be discriminatory.

* * * * *

63. Section 423.112 is amended by revising paragraph (a) to read as follows:

§ 423.112 Establishment of prescription drug plan sponsor service areas.

(a) *Service area for prescription drug plan sponsors.* The service area for a prescription drug plan sponsor other than a fallback prescription drug plan sponsor consists of one or more PDP regions as established under paragraphs (b) and (c) of this section.

* * * * *

64. Section 423.120 is amended by—

A. Revising paragraph (a).

B. Redesignating paragraph (b)(1)(ix) as paragraph (b)(1)(x).

C. Adding a new paragraph (b)(1)(ix).

D. Revising paragraph (b)(2)(v).

E. Adding new paragraph (b)(2)(vi).

F. Revising paragraph (b)(3).

G. Redesignating paragraph (c) as paragraph (c)(1).

H. Adding new paragraphs (c)(2) through (c)(4).

The revisions and additions read as follows:

§ 423.120 Access to covered Part D drugs.

(a) *Assuring pharmacy access—(1) Standards for convenient access to network pharmacies.* Except as provided in paragraph (a)(7) of this section, a Part D sponsor (as defined in § 423.4 of this part) must have a contracted pharmacy network consisting of retail pharmacies sufficient to ensure that, for beneficiaries residing in each State in a PDP sponsor’s service area (as defined in § 423.112(a) of this part), each State in a regional MA-organization’s service area (as defined in § 422.2 of this part), the entire service area of a local MA organization (as defined in § 422.2 of this chapter) or the entire geographic area of a cost contract (as defined in § 417.401 of this chapter) all of the following requirements are satisfied:

(i) At least 90 percent of Medicare beneficiaries, on average, in urban areas served by the Part D sponsor live within 2 miles of a network pharmacy that is a retail pharmacy or a pharmacy described under paragraph (a)(2) of this section.

(ii) At least 90 percent of Medicare beneficiaries, on average, in suburban areas served by the Part D sponsor live within 5 miles of a network pharmacy that is a retail pharmacy or a pharmacy described under paragraph (a)(2) of this section.

(iii) At least 70 percent of Medicare beneficiaries, on average, in rural areas served by the Part D sponsor live within 15 miles of a network pharmacy that is a retail pharmacy or a pharmacy described under paragraph (a)(2) of this section.

(2) *Applicability of some non-retail pharmacies to standards for convenient access.* Part D sponsors may count

I/T/U pharmacies and pharmacies operated by Federally Qualified Health Centers and Rural Health Centers toward the standards for convenient access to network pharmacies in paragraph (a)(1) of this section.

(3) *Access to non-retail pharmacies.* A Part D sponsor's contracted pharmacy network may be supplemented by non-retail pharmacies, including pharmacies offering home delivery via mail-order and institutional pharmacies, provided the requirements of paragraph (a)(1) of this section are met.

(4) *Access to home infusion pharmacies.* A Part D sponsor's contracted pharmacy network must provide adequate access to home infusion pharmacies consistent with written policy guidelines and other CMS instructions. A Part D plan must ensure that such network pharmacies, at a minimum meet all the following requirements:

(i) Are capable of delivering home-infused drugs in a form that can be administered in a clinically appropriate fashion.

(ii) Are capable of providing infusible Part D drugs for both short-term acute care and long-term chronic care therapies.

(iii) Ensure that the professional services and ancillary supplies necessary for home infusion therapy are in place before dispensing Part D home infusion drugs.

(iv) Provide delivery of home infusion drugs within 24 hours of discharge from an acute care setting, or later if so prescribed.

(5) *Access to long-term care pharmacies.* A Part D sponsor must offer standard contracting terms and conditions, including performance and service criteria for long-term care pharmacies that CMS specifies, to all long-term care pharmacies in its service area. The sponsor must provide convenient access to long-term care pharmacies consistent with written policy guidelines and other CMS instructions.

(6) *Access to I/T/U pharmacies.* A Part D sponsor must offer standard contracting terms and conditions conforming to the model addendum that CMS develops, to all I/T/U pharmacies in its service area. The sponsor must provide convenient access to I/T/U pharmacies consistent with written policy guidelines and other CMS instructions.

(7) *Waiver of pharmacy access requirements.* CMS waives the requirements under paragraph (a)(1) of this section in the case of either of the following:

(i) An MA organization or cost contract (as described in section 1876(h) of the Act) that provides its enrollees with access to covered Part D drugs through pharmacies owned and operated by the MA organization or cost contract, provided the organization's or plan's pharmacy network meets the access standard set forth—

(A) At § 422.112 of this chapter for an MA organization; or

(B) At § 417.416(e) of this chapter for a cost contract.

(ii) An MA organization offering a private fee-for-service plan described in § 422.4 of this chapter that—

(A) Offers qualified prescription drug coverage; and

(B) Provides plan enrollees with access to covered Part D drugs dispensed at all pharmacies, without regard to whether they are contracted network pharmacies and without charging cost-sharing in excess of that described in § 423.104(d)(2) and (d)(5).

(8) Pharmacy network contracting requirements. In establishing its contracted pharmacy network, a Part D sponsor offering qualified prescription drug coverage—

(i) Must contract with any pharmacy that meets the Part D sponsor's standard terms and conditions; and

(ii) May not require a pharmacy to accept insurance risk as a condition of participation in the Part D sponsor's contracted pharmacy network.

(9) *Differential cost-sharing for preferred pharmacies.* A Part D sponsor offering a Part D plan that provides coverage other than defined standard coverage may reduce copayments or coinsurance for covered Part D drugs obtained through a preferred pharmacy relative to the copayments or coinsurance applicable for such drugs when obtained through a non-preferred pharmacy. Such differentials are taken into account in determining whether the requirements under § 423.104(d)(2) and (d)(5) and § 423.104(e) are met. Any cost-sharing reduction under this section must not increase CMS payments to the Part D plan under § 423.329.

(10) *Level playing field between mail-order and network pharmacies.* A Part D sponsor must permit its Part D plan enrollees to receive benefits, which may include a 90-day supply of covered Part D drugs, at any of its network pharmacies that are retail pharmacies. A Part D sponsor may require an enrollee obtaining a covered Part D drug at a network pharmacy that is a retail pharmacy to pay any higher cost-sharing applicable to that covered Part D drug at the network pharmacy that is a retail pharmacy instead of the cost-sharing

applicable to that covered Part D drug at the network pharmacy that is a mail-order pharmacy.

(b) * * *

(1) * * *

(ix) Reviews and approves all clinical prior authorization criteria, step therapy protocols, and quantity limit restrictions applied to each covered Part D drug.

* * * * *

(2) * * *

(v) Beginning with contract year 2011, except as provided in paragraph (b)(2)(vi) of this section, a Part D sponsor's formulary will include all Part D drugs in a category or class for which both of the following apply:

(A) Restricted access to the drugs in the category or class would have major or life threatening clinical consequences for individuals who have a disease or disorder treated by drugs in such category or class; and

(B) There is a significant need for such individuals to have access to multiple drugs within a category or class due to unique chemical actions and pharmacological effects of the drugs within a category or class.

(vi) Exceptions to paragraph (b)(2)(v) of this section are as follows:

(A) Drug products that are rated as therapeutically equivalent (under the Food and Drug Administration's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations," also known as the Orange Book).

(B) Utilization management processes that limit the quantity of drugs due to safety.

(C) Other drugs that CMS specifies through a process that is based upon scientific evidence and medical standards of practice (and, in the case of antiretroviral medications, is consistent with the Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents) and which permits public notice and comment.

(3) *Transition process.* A Part D sponsor must provide for an appropriate transition process for enrollees prescribed Part D drugs that are not on its Part D plan's formulary (including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a plan's utilization management rules). The transition process must:

(i) Be applicable to all of the following:

(A) New enrollees into Part D plans following the annual coordinated election period.

(B) Newly eligible Medicare enrollees from other coverage.

(C) Individuals who switch from one plan to another after the start of the contract year.

(D) Current enrollees remaining in the plan affected by formulary changes.

(ii) Ensure access to a temporary supply of drugs within the first 90 days of coverage under a new plan. This 90-day timeframe applies to retail, home infusion, long-term care and mail-order pharmacies,

(iii) Ensure the provision of a temporary fill when an enrollee requests a fill of a non-formulary drug during the time period specified in paragraph (ii) of this paragraph (including Part D drugs that are on a plan's formulary but require prior authorization or step therapy under a plan's utilization management rules).

(A) In the outpatient setting, the one-time, temporary supply of non-formulary Part D drugs (including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a sponsor's utilization management rules) must be for at least 30 days of medication, unless the prescription is written by a prescriber for less than 30 days and requires the Part D sponsor to allow multiple fills to provide up to a total of 30 days of medication.

(B) In the long-term care setting, the temporary supply of non-formulary Part D drugs (including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a sponsor's utilization management rules) must be for up to 90 days in 31-day supply increments (unless the prescription is written for less than 31 days).

(iv) Ensure written notice is provided to each affected enrollee within 3 business days of the temporary fill.

(v) Ensure that reasonable efforts are made to notify prescribers of affected enrollees who receive a transition notice under paragraph (b)(3)(iv) of this section.

(c) * * *

(2) When processing Part D claims, a Part D sponsor or its intermediary must comply with the electronic transaction standards established by 45 CFR 162.1102. CMS will issue guidance on the use of conditional fields within such standards.

(3) A Part D sponsor must require its network pharmacies to submit claims to the Part D sponsor or its intermediary whenever the card described in paragraph (c)(1) of this section is presented or on file at the pharmacy unless the enrollee expressly requests that a particular claim not be submitted to the Part D sponsor or its intermediary.

(4) A part D sponsor must assign a unique—

(i) Part D BIN or RxBIN and Part D processor control number (RxPCN) combination to its Medicare line of business; and

(ii) Part D cardholder identification number (RxID) to each Medicare Part D enrollee to clearly identify Medicare Part D beneficiaries.

65. Section 423.128 is amended by adding a new paragraph (f) to read as follows:

§ 423.128 Dissemination of Part D plan information.

* * * * *

(f) *Disclosure requirements.* CMS may require a Part D plan sponsor to disclose to its enrollees or potential enrollees, the Part D plan sponsor's performance and contract compliance deficiencies in a manner specified by CMS.

66. Section 423.132 is amended by—

A. Revising the introductory text of paragraph c.

B. In paragraphs (c)(2) and (c)(3), removing the “;” and adding a “.” in its place.

C. In paragraph (c)(4), removing “; and” and adding a “.” in its place.

D. Redesignating paragraph (c)(5) as (c)(6).

E. Adding a new paragraph (c)(5).

F. Revising paragraph (d).

The revisions and additions read as follows:

§ 423.132 Public disclosure of pharmaceutical prices for equivalent drugs.

* * * * *

(c) Waiver of public disclosure requirement. CMS waives the requirement under paragraph (a) of this section in any of the following cases:

* * * * *

(5) A long-term care network pharmacy.

(d) *Modification of timing requirement.* CMS modifies the requirement under paragraph (b) of this section under circumstances where CMS deems compliance with this requirement to be impossible or impracticable.

Subpart D—Cost Control and Quality Improvement Requirements

67. Section 423.153 is amended by—

A. Adding paragraphs (d)(1)(v) through (vii).

B. Revising paragraph (d)(2).

The additions and revisions read as follows:

§ 423.153 Drug utilization management, quality assurance, and medication therapy management programs (MTMPs).

* * * * *

(d) * * *

(1) * * *

(v) Must enroll targeted beneficiaries using an opt-out method of enrollment only.

(vi) Must target beneficiaries for enrollment in the MTMP at least quarterly during each plan year.

(vii) Must offer a minimum level of medication therapy management services for each beneficiary enrolled in the MTMP that includes all of the following:

(A) Interventions for both beneficiaries and prescribers.

(B) Annual comprehensive medication reviews with written summaries. The comprehensive medical review must include an interactive, person-to-person consultation performed by a pharmacist or other qualified provider unless the beneficiary is in a long-term care setting.

(C) Quarterly targeted medication reviews with follow-up interventions when necessary.

(2) *Targeted beneficiaries.* Targeted beneficiaries for the MTMP described in paragraph (d)(1) of this section are enrollees in the sponsor's Part D plan who—

(i) Have multiple chronic diseases, with three chronic diseases being the maximum number a Part D plan sponsor may require for targeted enrollment;

(ii) Are taking multiple Part D drugs, with eight Part D drugs being the maximum number of drugs a Part D plan sponsor may require for targeted enrollment; and

(iii) Are likely to incur costs for covered Part D drugs that exceed the initial coverage limit for the Part D defined standard benefit for the applicable Part D plan year.

* * * * *

68. Section 423.156 is revised to read as follows:

§ 423.156 Consumer satisfaction surveys.

Part D contracts with 600 or more enrollees as of July of the prior year must contract with approved Medicare Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey vendors to conduct the Medicare CAHPS satisfaction survey of Part D plan enrollees in accordance with CMS specifications and submit the survey data to CMS.

69. Section 423.165 is amended by—

A. Removing paragraph (b)(4).

B. Revising paragraph (f).

The revision reads as follows:

§ 423.165 Compliance deemed on the basis of accreditation.

* * * * *

(f) *Authority.* Nothing in this limits CMS' authority under subparts K and O

of this part, including, but not limited to the ability to impose intermediate sanctions, civil money penalties, and terminate a contract with a Part D plan sponsor.

Subpart F—Submission of Bids and Monthly Beneficiary Premiums: Plan Approval

70. Section 423.265 is amended by revising paragraph (b) to read as follows:

§ 423.265 Submission of bids and related information.

* * * * *

(b) *Bid submission.* (1) General. Not later than the first Monday in June, each potential Part D sponsor must submit bids and supplemental information described in this section for each Part D plan it intends to offer in the subsequent calendar year.

(2) *Substantial differences between bids.* Potential Part D sponsors' bid submissions must reflect differences in benefit packages and plan costs that CMS determines to represent substantial differences relative to a sponsor's other bid submissions. In order to be considered "substantially different," each bid must be significantly different from the sponsor's other bids with respect to beneficiary out-of-pocket costs and formulary structures.

* * * * *

71. Section 423.272 is amended by adding a new paragraph (b)(3) to read as follows:

§ 423.272 Review and negotiation of bid and approval of plans submitted by potential Part D sponsors.

* * * * *

(b) * * *

(3) *Substantial differences between bids—(i) General.* CMS approves a bid only if it finds that the benefit package and plan costs represented by that bid are substantially different as provided under § 423.265 (b)(2) of this subpart from the benefit package represented by another bid submitted by the same Part D sponsor.

(ii) *Transition period for PDP sponsors with new acquisitions.* After a 2-year transition period, as determined by CMS, CMS approves a bid offered by a PDP sponsor (or by a parent organization to that PDP sponsor) that recently purchased (or otherwise acquired or merged with) another Part D sponsor if it finds that the benefit package and plan costs represented by that bid are substantially different from any benefit package and plan costs represented by another bid submitted by the same Part D sponsor (or parent organization to that Part D sponsor).

* * * * *

Subpart G—Payments to Part D Plan Sponsors for Qualified Prescription Drug Coverage

§ 423.308 [Amended]

72. Section 423.308 is amended in paragraph (1) of the definition of "gross covered prescription drug costs" by removing the phrase "The share of negotiated prices" and adding in its place "The share of actual costs".

Subpart J—Coordination Under Part D Plans With Other Prescription Drug Coverage

73. Section 423.462 is amended by—
A. Redesignating the existing text as paragraph (a).

B. Adding a paragraph heading for paragraph (a) and new paragraph (b).
The additions read as follows:

§ 423.462 Medicare secondary payer procedures.

* * * * *

(a) *General rule.* * * *

(b) *Reporting requirements.* A Part D sponsor must report credible new or changed primary payer information to the CMS Coordination of Benefits Contractor in accordance with the processes and timeframes specified by CMS.

74. Section 423.464 is amended by adding new paragraphs (a)(3), (e)(1)(vi), and (g) to read as follows:

§ 423.464 Coordination of benefits with other providers of prescription drug coverage.

(a) * * *

(3) Retroactive claims adjustments, underpayment reimbursements, and overpayment recoveries as described in paragraph (g) of this section and § 423.466(a) of this subpart.

* * * * *

(e) * * *

(1) * * *

(vi) Does not engage in midyear plan or noncalendar year plan enrollment changes on behalf of a substantial number of its members when authorized to do so on the beneficiary's behalf.

* * * * *

(g) *Responsibility to account for other providers of prescription drug coverage when a retroactive claims adjustment creates an overpayment or underpayment.* When a Part D sponsor makes a retroactive claims adjustment, the sponsor has the responsibility to account for SPAPs and other entities providing prescription drug coverage in reconciling the claims adjustments that create overpayments or underpayments. In carrying out these reimbursements and recoveries, Part D sponsors must also account for payments made, and for

amounts being held for payment, by other individuals or entities. Part D sponsors must have systems to track and report adjustment transactions and to support all of the following:

(1) Adjustments involving payments by other plans and programs providing prescription drug coverage have been made.

(2) Reimbursements for excess cost-sharing and premiums for low-income subsidy eligible individuals have been processed in accordance with the requirements in § 423.800(c).

(3) Recoveries of erroneous payments for enrollees as specified in § 423.464(f)(4) have been sought.

75. A new § 423.466 is added to subpart J to read as follows:

§ 423.466 Timeframes for coordination of benefits.

(a) *Retroactive claims adjustments, underpayment refunds, and overpayment recoveries.* Whenever a sponsor receives information that necessitates a retroactive claims adjustment, the sponsor must process the adjustment and issue refunds or recovery notices within 45 days of the sponsor's receipt of complete information regarding claims adjustment.

(b) *Coordination of benefits.* Part D sponsors must coordinate benefits with SPAPs, other entities providing prescription drug coverage, beneficiaries, and others paying on the beneficiaries' behalf for a period not to exceed 3 years from the date on which the prescription for a covered Part D drug was filled.

Subpart K—Application Procedures and Contracts With PDP Sponsors

76. Section 423.502 is amended by—
A. Redesignating paragraphs (b) through (d) as (c) through (e), respectively

B. Adding a new paragraph (b).

C. Revising newly redesignated paragraph (c)(1) introductory text and paragraph (c)(2).

The addition and revisions reads as follows:

§ 423.502 Application requirements.

* * * * *

(b) *Completion of a notice of intent to apply.*

(1) An organization submitting an application under this section for a particular contract year must first submit a completed Notice of Intent to Apply by the date established by CMS. CMS will not accept applications from organizations that do not submit a timely Notice of Intent to Apply.

(2) Submitting a Notice of Intent to Apply does not bind that organization to submit an application for the applicable contract year.

(c) * * *

(1) In order to obtain a determination on whether it meets the requirements to become a Part D plan sponsor, an entity, or an individual authorized to act for the entity (the applicant), must fully complete all parts of a certified application in the form and manner required by CMS, including the following:

* * * * *

(2) The authorized individual must describe thoroughly how the entity is qualified to meet the all requirements described in this part.

* * * * *

77. Section 423.503 is amended by—
A. Revising paragraphs (a)(1), (a)(2), and (b).

B. Adding a new paragraph (c)(2)(iii).

C. Revising paragraph (c)(3)(iii).

D. Removing paragraph (d).

The revisions and addition read as follows:

§ 423.503 Evaluation and determination procedures for applications to be determined qualified to act as a sponsor.

* * * * *

(a) * * *

(1) With the exception of evaluations conducted under paragraph (b) of this section, CMS evaluates an entity's application solely on the basis of information contained in the application itself and any additional information that CMS obtains through on-site visits.

(2) After evaluating all relevant information, CMS determines whether the application meets all the requirements described in this part.

(b) *Use of information from a current or prior contract.* If a Part D plan sponsor fails during the 14 months preceding the deadline established by CMS for the submission of contract qualification applications (or in the case of a fallback entity, the previous 3-year contract) to comply with the requirements of the Part D program under any current or prior contract with CMS under title XVIII of the Act or fails to complete a corrective action plan during the 14 months preceding the deadline established by CMS for the submission of contract qualification applications, CMS may deny an application based on the applicant's failure to comply with the requirements of the Part D program under any current or prior contract with CMS even if the applicant currently meets all of the requirements of this part.

(c) * * *

(2) * * *

(iii) If CMS does not receive a revised application within 10 days from the date of the notice, or if after timely submission of a revised application, CMS still finds the applicant does not appear qualified to contract as a Part D plan sponsor or has not provided enough information to allow CMS to evaluate the application, CMS denies the application.

(3) * * *

(iii) The applicant's right to request a hearing in accordance with the procedures specified in subpart N of this part.

78. Section 423.504 is amended by—

A. Revising paragraph (b)(4)(vi).

B. Redesignating paragraph (b)(6) as paragraph (b)(7).

C. Adding a new paragraph (b)(6).

The revisions and addition read as follows:

§ 423.504 General provisions.

* * * * *

(b) * * *

(4) * * *

(vi) Adopt and implement an effective compliance program, which must include measures that prevent, detect, and correct noncompliance with CMS' program requirements as well as measures that prevent, detect, and correct fraud, waste, and abuse. The compliance program must, at a minimum, include the following core requirements:

(A) Written policies, procedures, and standards of conduct that—

(1) Articulate the Part D plan sponsor's commitment to comply with all applicable Federal and State standards;

(2) Describe compliance expectations as embodied in the standards of conduct;

(3) Implement the operation of the compliance program;

(4) Provide guidance to employees and others on dealing with potential compliance issues;

(5) Identify how to communicate compliance issues to appropriate compliance personnel;

(6) Describe how potential compliance issues are investigated and resolved by the Part D plan sponsor; and

(7) Include a policy of non-intimidation and non-retaliation for good faith participation in the compliance program, including but not limited to reporting potential issues, investigating issues, conducting self-evaluations, audits and remedial actions, and reporting to appropriate officials.

(B) The designation of a compliance officer and a compliance committee

who report directly to the Part D plan sponsor's chief executive or other senior administrator.

(1) The compliance officer, vested with the day-to-day operations of the compliance program, must be an employee of the Part D plan sponsor.

(2) The compliance officer and the compliance committee must periodically report directly to the governing body of the Part D plan sponsor on the activities and status of the compliance program, including issues identified, investigated, and resolved by the compliance program.

(3) The governing body of the Part D plan sponsor must be knowledgeable about the content and operation of the compliance program and must exercise reasonable oversight with respect to the implementation and effectiveness of the compliance programs.

(C)(1) Each Part D plan sponsor must establish, implement and provide effective training and education for its employees including, the chief executive and senior administrators or managers; governing body members; and first tier, downstream, and related entities.

(2) The training and education must occur at a least annually and be a part of the orientation for new employees including, the chief executive and senior administrators or managers; governing body members; and first tier, downstream, and related entities.

(D) Establishment and implementation of effective lines of communication, ensuring confidentiality, between the compliance officer, members of the compliance committee, the Part D plan sponsor's employees, managers and governing body, and the Part D plan sponsor's first tier, downstream, and related entities. Such lines of communication must be accessible to all and allow compliance issues to be reported including a method for anonymous and confidential good faith reporting of potential compliance issues as they are identified.

(E) Well-publicized disciplinary standards through the implementation of procedures which encourage good faith participation in the compliance program by all affected individuals. These standards must include policies that—

(1) Articulate expectations for reporting compliance issues and assist in their resolution;

(2) Identify non-compliance or unethical behavior; and

(3) Provide for timely, consistent, and effective enforcement of the standards when non-compliance or unethical behavior is determined.

(F) Establishment and implementation of an effective system for routine monitoring and identification of compliance risks. The system should include internal monitoring and audits and, as appropriate, external audits, to evaluate the Part D plan sponsors, including first tier entities', compliance with CMS requirements and the overall effectiveness of the compliance program.

(G) Establishment and implementation of procedures and a system for promptly responding to compliance issues as they are raised, investigating potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence, and ensure ongoing compliance with CMS requirements.

* * * * *

(6) Not have terminated a contract by mutual consent under which, as a condition of the consent, the Part D plan sponsor agreed that it was not eligible to apply for new contracts or service area expansions for a period up to 2 years per § 423.508(e) of this subpart.

* * * * *

79. Section 423.505 is amended by—

A. Redesignating paragraph (e)(1)(ii) and (e)(1)(iii) as paragraph (e)(1)(iii) and (e)(1)(iv), respectively.

B. Adding a new paragraph (e)(1)(ii).

C. Revising newly redesignated paragraph (e)(1)(iii).

D. Revising paragraph (f)(3) introductory text.

E. Revising paragraphs (i)(2)(i) and (m)(1)(iii)(C).

F. Add a new paragraph (n).

The additions and revisions read as follows:

§ 423.505 Contract provisions.

* * * * *

(e) * * *

(1) * * *

(ii) Compliance with CMS requirements for maintaining the privacy and security of personal health information and other personally identifiable information of Medicare enrollees;

(iii) The facilities of the Part D sponsor to include computer and other electronic systems; and

* * * * *

(f) * * *

(3) All data elements included in all its drug claims for purposes deemed necessary and appropriate by the Secretary, including, but not limited to the following:

* * * * *

(i) * * *

(2) * * *

(i) HHS, the Comptroller General, or their designees have the right to audit, evaluate, and inspect any books, contracts, computer or other electronic systems, including medical records and documentation of the first tier, downstream, and related to CMS' contract with the Part D sponsor.

* * * * *

(m)(1) * * *

(iii) * * *

(C) Plan identifier elements on the claim are encrypted or unavailable for release to external entities with the exception of HHS grantees that CMS determines meet all of the following criteria:

(1) The plan identifier is essential to the study.

(2) The study is key to the mission of the sponsoring agency.

(3) The study provides significant benefit to the Medicare program.

(4) The requestor attests that any public findings or publications will not identify plans.

* * * * *

(n)(1) CMS may determine that a Part D plan sponsor is out of compliance with a Part D requirement when the sponsor fails to meet performance standards articulated in the Part D statutes, regulations, or guidance.

(2) If CMS has not already articulated a measure for determining noncompliance, CMS may determine that a Part D sponsor is out of compliance when its performance represents an outlier relative to the performance of other Part D sponsors.

80. Section 423.507 is amended by—

A. Revising paragraph (a)(2)(ii).

B. Removing paragraph (a)(2)(iii).

C. Adding a new paragraph (b)(1)(iii).

D. Revising paragraph (b)(2)(ii).

E. Removing (b)(2)(iii).

F. Redesignating paragraph (b)(2)(iv) as (b)(2)(iii).

G. In newly redesignated paragraph (b)(2)(iii), removing the reference "paragraphs (b)(2)(ii) and (iii) of this section" and add the reference "paragraph (b)(2)(ii) of this section" in its place.

H. Revising paragraph (b)(3).

The revisions and addition read as follows:

§ 423.507 Nonrenewal of a contract.

(a) * * *

(2) * * *

(ii) Each Medicare enrollee by mail at least 90 calendar days before the date on which the nonrenewal is effective. The sponsor must also provide information about alternative enrollment options by doing one or more of the following:

(A) Provide a CMS approved written description of alternative PDP plan options available for obtaining qualified prescription drug coverage within the beneficiaries' region.

(B) Place outbound calls to all affected enrollees to ensure beneficiaries know who to contact to learn about their enrollment options.

* * * * *

(b) * * *

(1) * * *

(iii) The contract must be nonrenewed as to an individual PDP if that plan does not have a sufficient number of enrollees to establish that it is a viable independent plan option.

(2) * * *

(ii) To each of the Part D plan sponsor's Medicare enrollees by mail at least 90 calendar days before the date on which the nonrenewal is effective, or at the conclusion of the appeals process if applicable.

* * * * *

(3) *Opportunity to develop and implement a corrective action plan.* (i)

Before providing a notice of intent of nonrenewal of the contract, CMS will provide the Part D plan sponsor with a notice specifying the deficiencies and reasonable opportunity to develop and implement a corrective action plan to correct the deficiencies that form the basis for the determination to non-renew the contract.

(ii) CMS affords the Part D plan sponsor at least 30 calendar days in which to develop and implement a corrective action plan to correct the deficiencies that formed the basis for the determination to nonrenew the contract.

(iii) The Part D plan sponsor is solely responsible for the identification, development, and implementation of its corrective action plan and for demonstrating to CMS that the underlying deficiencies have been corrected within the time period specified by CMS in the notice requesting corrective action.

* * * * *

81. Section 423.508 is amended by adding a new paragraph (e) to read as follows:

§ 423.508 Modification or termination of contract by mutual consent.

* * * * *

(e) *Agreement to limit new Part D applications.* As a condition of the consent to a mutual termination, CMS will require, as a provision of the termination agreement language prohibiting the Part D plan sponsor from applying for new contracts or service area expansions for a period up to 2 years, absent circumstances warranting special consideration.

82. Amend § 423.509 by revising paragraphs (a), introductory text of paragraph (b), (b)(2), and (c) to read as follows:

§ 423.509 Termination of contract by CMS.

(a) *Termination by CMS.*

(1) CMS may at any time terminate a contract if CMS determines that the Part D plan sponsor meets any of the following:

(i) Has failed substantially to carry out the contract.

(ii) Is carrying out the contract in a manner that is inconsistent with the efficient and effective administration of this part.

(iii) No longer substantially meets the applicable conditions of this part.

(2) CMS may determine, in accordance with paragraph (a)(1) of this section, that a basis exists to terminate a Part D sponsor's contract if—

(i) The Part D plan sponsor fails to comply with any of the regulatory requirements contained in this part.

(ii) The Part D plan sponsor fails to meet CMS performance requirements in carrying out the regulatory requirements contained in this part, including, but not limited to, when CMS determines that an analysis of data related to the sponsor's performance indicates it is an outlier relative to that of other sponsors; or

(iii) There is credible evidence to show that the Part D plan sponsor has committed or participated in false, fraudulent, or abusive activities affecting the Medicare, Medicaid, or other State or Federal health care programs, including submission of false or fraudulent data.

(b) *Notice.* If CMS decides to terminate a contract it gives notice of the termination as follows:

* * * * *

(2) *Expedited termination of contract by CMS.* (i) If CMS determines that a delay in termination, resulting from compliance with the procedures provided in this part prior to termination, would pose an imminent and serious risk to the health of the individuals enrolled with the Part D plan sponsor the effective date of termination will be specified, in writing, by CMS.

(ii) If a termination is effective in the middle of a month, CMS has the right to recover the prorated share of the capitation payments made to the Part D plan sponsor covering the period of the month following the contract termination.

* * * * *

(c) *Opportunity to develop and implement a corrective action plan.*

(1) *General.* (i) Before providing a notice of intent to terminate the contract, CMS will provide the Part D plan sponsor with a notice specifying the deficiencies and reasonable opportunity to develop and implement a corrective action plan to correct the deficiencies that form the basis for the determination to terminate the contract.

(ii) CMS will afford the Part D plan sponsor at least 30 calendar days in which to develop and implement a corrective action plan to correct the deficiencies that formed the basis for the determination to terminate the contract.

(iii) The Part D plan sponsor is solely responsible for the identification, development, and implementation of its corrective action plan and for demonstrating to CMS that the underlying deficiencies have been corrected within the time period specified by CMS in the notice requesting corrective action.

(2) *Exceptions.* If CMS determines that a delay in termination, resulting from compliance with the procedures provided in this part prior to termination, would pose an imminent and serious risk to the health of the individuals enrolled with the Part D plan sponsor, the Part D plan sponsor will not be provided with an opportunity to develop and implement a corrective action plan prior to termination.

* * * * *

83. Section 423.514 is amended by—

A. Revising the section heading.

B. Adding a new paragraph (g).

The revision and addition to read as follows:

§ 423.514 Validation of Part D reporting requirements.

* * * * *

(g) *Data validation.* Each Part D sponsor must subject information collected under paragraph (a) of this section to a yearly independent audit to determine its reliability, validity, completeness, and comparability in accordance with specifications developed by CMS.

Subpart L—Effect of Change of Ownership or Leasing of Facilities During Term of Contract

84. Section 423.551 is amended by adding a new paragraph (g) to read as follows:

§ 423.551 General provisions.

* * * * *

(g) *Sale of beneficiaries not permitted.*

(1) CMS will only recognize the sale or transfer of an organization's entire PDP line of business, consisting of all PDP contracts held by the PDP sponsor.

(2) CMS will not recognize or allow a sale or transfer that consists solely of the sale or transfer of individual beneficiaries, groups of beneficiaries enrolled in a pharmacy benefit package, or one contract if the sponsor holds more than one PDP contract.

Subpart M—Grievances, Coverage Determinations, and Appeals

85. Section 423.568 is revised to read as follows:

§ 423.568 Standard timeframe and notice requirements for coverage determinations.

(a) *Method and place for filing a request.* An enrollee must ask for a standard coverage determination by making a request with the Part D plan sponsor in accordance with the following:

(1) Except as specified in paragraph (a)(2) of this section, the request may be made orally or in writing.

(2) Requests for payment must be made in writing (unless the Part D plan sponsor has implemented a voluntary policy of accepting oral payment requests).

(b) *Timeframe for requests for drug benefits.* When a party makes a request for a drug benefit, the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the request, or, for an exceptions request, the physician's or other prescriber's supporting statement.

(c) *Timeframe for requests for payment.* When a party makes a request for payment, the Part D plan sponsor must notify the enrollee of its determination and make payment (when applicable) no later than 14 calendar days after receipt of the request.

(d) *Written notice for favorable decisions by a Part D plan sponsor.* If a Part D plan sponsor makes a completely favorable decision under paragraph (b) of this section, it must give the enrollee written notice of the determination. The initial notice may be provided orally, so long as a written follow-up notice is sent within 3 calendar days of the oral notification.

(e) *Form and content of the approval notice.* The notice of any approval under paragraph (d) of this section must explain the conditions of the approval in a readable and understandable form.

(f) *Written notice for denials by a Part D plan sponsor.* If a Part D plan sponsor decides to deny a drug benefit, in whole or in part, it must give the enrollee written notice of the determination.

(g) *Form and content of the denial notice.* The notice of any denial under paragraph (f) of this section must meet the following requirements:

(1) Use approved notice language in a readable and understandable form.

(2) State the specific reasons for the denial.

(i) For drug coverage denials, describe both the standard and expedited redetermination processes, including the enrollee's right to, and conditions for, obtaining an expedited redetermination and the rest of the appeals process.

(ii) For payment denials, describe the standard redetermination process and the rest of the appeals process.

(3) Inform the enrollee of his or her right to a redetermination.

(4) Comply with any other notice requirements specified by CMS.

(h) *Effect of failure to meet the adjudicatory timeframes.* If the Part D plan sponsor fails to notify the enrollee of its determination in the appropriate timeframe under paragraphs (b) or (c) of this section, the failure constitutes an adverse coverage determination, and the plan sponsor must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe.

86. Section 423.570 is amended by revising paragraph (d)(1) to read as follows:

§ 423.570 Expediting certain coverage determinations.

* * * * *

(d) * * *

(1) Make the determination within the 72 hour timeframe established in § 423.568(b) for a standard determination. The 72 hour period begins on the day the Part D plan sponsor receives the request for expedited determination, or, for an exceptions request, the physician's or other prescriber's supporting statement.

* * * * *

87. Section 423.572 is amended by revising paragraphs (b) and (c) to read as follows:

§ 423.572 Timeframes and notice requirements for expedited coverage determinations.

* * * * *

(b) *Confirmation of oral notice.* If the Part D plan sponsor first notifies an enrollee of an adverse or favorable expedited determination orally, it must mail written confirmation to the enrollee within 3 calendar days of the oral notification.

(c) *Content of the notice of expedited determination.* (1) If the determination is completely favorable to the enrollee,

the notice must explain the conditions of the approval in a readable and understandable form.

(2) If the determination is not completely favorable to the enrollee, the notice must—

(i) Use approved language in a readable and understandable form;

(ii) State the specific reasons for the denial;

(iii) Inform the enrollee of his or her right to a redetermination;

(iv) Describe—

(A) Both the standard and expedited redetermination processes, including the enrollee's right to request an expedited redetermination;

(B) Conditions for obtaining an expedited redetermination; and

(C) Other aspects of the appeal process.

* * * * *

88. Section 423.590 is amended by—

A. Redesignating paragraph (d)(2) as paragraph (d)(3).

B. Adding a new paragraph (d)(2).

C. Revising the introductory text of paragraph (g).

D. Adding a new paragraph (h).

The revisions and additions read as follows:

§ 423.590 Timeframes and responsibility for making redeterminations.

* * * * *

(d) * * *

(2) *Confirmation of oral notice.* If the Part D plan sponsor first notifies an enrollee of an adverse or favorable expedited redetermination orally, it must mail written confirmation to the enrollee within 3 calendar days of the oral notification.

* * * * *

(g) *Form and content of an adverse redetermination notice.* The notice of any adverse determination under paragraphs (a)(2), (b)(2), (d)(1) or (d)(2) of this section must—

* * * * *

(h) *Form and content of a completely favorable redetermination notice.* The notice of any completely favorable determination under paragraphs (a)(1), (d)(1) or (d)(2) of this section must explain the conditions of the approval in a readable and understandable form.

Subpart N—Medicare Contract Determinations and Appeals

89. Section 423.642 is amended by revising paragraph (c) to read as follows:

§ 423.642 Notice of contract determination.

* * * * *

(c) *CMS-initiated terminations—(1) General rule.* CMS mails notice to the Part D plan sponsor 90 calendar days

before the anticipated effective date of the termination.

(2) *Exception.* For terminations where CMS determines that a delay in termination, resulting from compliance with the procedures provided in this part prior to termination, would pose an imminent and serious risk to the health of the individuals enrolled with the Part D plan sponsor, CMS notifies the Part D plan sponsor of the date that it will terminate the Part D plan sponsor's contract.

* * * * *

90. Section 423.650 is revised to read as follows:

§ 423.650 Right to a hearing, burden of proof, standard of proof, and standards of review.

(a) *Right to a hearing.* The following parties are entitled to a hearing:

(1) A contract applicant that has been determined to be unqualified to enter into a contract with CMS under Part D of Title XVIII of the Act in accordance with § 423.502 and § 423.503 of this part.

(2) A Part D sponsor whose contract has been terminated under § 423.509 of this part.

(3) A Part D sponsor whose contract has not been renewed in accordance with § 423.507 of this part.

(4) A Part D sponsor who has had an intermediate sanction imposed in accordance with § 423.752(a) and (b) of this part.

(b) *Burden of proof, standard of proof, and standard of review at hearing.*

(1) During a hearing to review a contract determination as described at § 423.641(a) of this subpart, the applicant has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of § 423.502 and § 423.503 of this part.

(2) During a hearing to review a contract determination as described at § 423.641(b) of this part, the Part D plan sponsor has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of § 423.507 of this part.

(3) During a hearing to review a contract determination as described at § 423.641(c) of this subpart, the Part D plan sponsor has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of § 423.509 of this part.

(4) During a hearing to review the imposition of an intermediate sanction as described at § 423.750 of this part, the Part D sponsor has the burden of proving by a preponderance of the

evidence that CMS' determination was inconsistent with the requirements of § 423.752 of this part.

(c) Timing of favorable decision. Notice of any decision favorable to the Part D sponsor appealing a determination that it is not qualified to enter into a contract with CMS must be issued by September 1 for the contract in question to be effective on January 1 of the following year.

* * * * *

91. Section 423.651 is amended by revising paragraphs (a) and (b) to read as follows:

§ 423.651 Request for hearing.

(a) *Method and place for filing a request.* (1) A request for a hearing must be made in writing and filed by an authorized official of the contract applicant or Part D plan sponsor that was the party to the determination under the appeal.

(2) The request for the hearing must be filed in accordance with the requirements specified in the notice.

(b) *Time for filing a request.* A request for a hearing must be filed within 15 calendar days after the receipt of the notice of the contract determination or intermediate sanction.

* * * * *

92. Section 423.652 is amended by revising paragraph (b)(2) to read as follows:

§ 423.652 Postponement of effective date of a contract determination when a request for a hearing is filed timely.

* * * * *

(b) * * *

(2) If CMS determines that a delay in termination, resulting from compliance with the procedures provided in this part prior to termination, would pose an imminent and serious risk to the health of individuals enrolled with the Part D plan sponsor, the date of termination will not be postponed if the Part D plan sponsor requests a hearing.

* * * * *

93. Section 423.655 is revised to read as follows:

§ 423.655 Time and place of hearing.

(a) The hearing officer—

(1) Fixes a time and place for the hearing, which is not to exceed 30 calendar days after the receipt of request for the hearing;

(2) Sends written notice to the parties that informs the parties of the general and specific issues to be resolved, the burden of proof, and information about the hearing procedure.

(b)(1) The hearing officer may, on his or her own motion, change the time and place of the hearing.

(2) The hearing officer may adjourn or postpone the hearing.

(c)(1) The Part D plan sponsor or CMS may request an extension by filing a written request no later than 5 calendar days prior to the scheduled hearing.

(2) When either the Part D plan sponsor or CMS requests an extension the hearing officer will provide a one-time 15-calendar day extension.

(3) Additional extensions may be granted at the discretion of the hearing officer.

94. Section 423.658 is amended by revising paragraph (d) to read as follows:

§ 423.658 Conduct of hearing.

* * * * *

(d) The Part D sponsor bears the burden of going forward and must first present evidence and argument before CMS presents its evidence and argument.

95. Section 423.661 is revised to read as follows:

§ 423.661 Witnesses lists and documents.

Witness lists and documents must be identified and exchanged at least 5 calendar days prior to the scheduled hearing.

96. Section 423.666 is amended by revising paragraphs (a) and (c) to read as follows:

§ 423.666 Review by the Administrator.

(a) *Request for review by Administrator.* CMS or a Part D plan sponsor that has received a hearing decision may request a review by the Administrator within 15 calendar days after receipt of the hearing decision as provided under § 423.665(b) of this subpart. Both the Part D plan sponsor and CMS may provide written arguments to the Administrator for review.

* * * * *

(c) *Notification of Administrator determination.* The Administrator notifies both parties of his or her determination regarding review of the hearing decision within 30 calendar days after receipt of request for review. If the Administrator declines to review the hearing decision or the Administrator does not make a determination regarding review within 30 calendar days, the decision of the hearing officer is final.

* * * * *

97. Section 423.668 is amended by revising the section heading and the paragraph heading for paragraph (a) to read as follows:

§ 423.668 Reopening of a contract determination or decision of a hearing officer or the Administrator.

(a) *Contract determination.* * * *

* * * * *

Subpart O—Intermediate Sanctions

98. Section 423.750 is amended by revising paragraph (a) to read as follows:

§ 423.750 Types of intermediate sanctions and civil money penalties.

(a) The following intermediate sanctions may be imposed and will continue in effect until CMS is satisfied that the deficiencies that are the basis for the sanction determination have been corrected and are not likely to recur:

(1) Suspension of the Part D plan sponsor's enrollment of Medicare beneficiaries.

(2) Suspension of payment to the Part D plan sponsor for Medicare beneficiaries enrolled after the date CMS notifies the organization of the intermediate sanction.

(3) Suspension of all marketing activities to Medicare beneficiaries by a Part D plan sponsor.

* * * * *

99. Section 423.752 is amended by—

A. Revising the paragraphs (a) introductory text, (a)(1), (a)(3), and (a)(4).

B. In paragraph (c)(1), removing the cross-reference "423.509(a)(4)" and adding the cross-reference "§ 422.509(a)(2)(iii) of this part" in its place.

C. In paragraph (c)(2)(ii), removing the phrase "pursuant to 423.509(a)(4)" and adding the phrase "under § 422.509(a)(2)(iii) of this part" in its place.

§ 423.752 Basis for imposing intermediate sanctions and civil money penalties.

(a) *All intermediate sanctions.* For the violations listed in this paragraph (a), CMS may impose one or more of the sanctions specified in § 423.750(a) of this subpart on any Part D plan sponsor with a contract. The Part D plan sponsor may also be subject to other remedies authorized under law.

(1) Fails substantially to provide medically necessary items and services that are required (under law or under the contract) to be provided to an individual covered under the contract, if the failure has adversely affected (or has the substantial likelihood of adversely affecting) the individual.

* * * * *

(3) Acts to expel or refuses to re-enroll a beneficiary in violation of the provisions of this part.

(4) Engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by this part) by eligible individuals with the organization whose medical condition or history indicates a need for substantial future medical services.

* * * * *

100. Section 423.756 is amended by—

- A. Revising paragraph (b).
B. Removing paragraph (c).
C. Redesignating paragraphs (d) through (f) as paragraphs (c) through (e), respectively.

D. Revising the newly redesignated paragraphs (c)(1) and (c)(3).

The revisions read as follows:

§ 423.756 Procedures for imposing intermediate sanctions and civil money penalties.

(b) Hearing. (1) The Part D plan sponsor may request a hearing before a CMS hearing officer.

(2) A written request must be received by the designated CMS office within 15 calendar days after the receipt of the notice.

(3) A request for a hearing under § 423.650 of this part does not delay the date specified by CMS when the sanction becomes effective.

(4) The Part D plan sponsor must follow the right to a hearing procedure as specified at § 423.650 through § 423.662 of this part.

(c) * * *

(1) Effective date. The effective date of the sanction is the date specified by CMS in the notice.

* * * * *

(3) Duration of sanction. The sanction remains in effect until CMS is satisfied that the deficiencies that are the basis for the sanction determination have been corrected and are not likely to recur.

(i) CMS may require that the Part D plan sponsor hire an independent auditor to provide CMS with additional information to determine if the deficiencies that are the basis for the sanction determination have been corrected and are not likely to recur. The independent auditor must work in accordance with CMS specifications and must be willing to attest that a complete and full independent review has been performed.

(ii) In instances where marketing or enrollment or both intermediate sanctions have been imposed, CMS may require a Part D plan sponsor to market or to accept enrollments or both for a limited period of time in order to assist CMS in making a determination as to whether the deficiencies that were the bases for the intermediate sanctions

have been corrected and are not likely to recur.

(A) If, following this time period, CMS determines the deficiencies have not been corrected or are likely to recur, the intermediate sanctions will remain in effect until such time that CMS is assured the deficiencies have been corrected and are not likely to recur.

(B) The Part D plan sponsor does not have a right to a hearing under § 423.650(a)(4) of this subpart to challenge CMS' determination to keep the intermediate sanctions in effect.

* * * * *

Subpart P—Premium and Cost-Sharing Subsidies for Low-Income Individuals

101. Section 423.773 is amended by revising paragraph (c)(2) to read as follows:

§ 423.773 Requirements for eligibility.

* * * * *

(c) * * *

(2) CMS notifies an individual treated as a full-subsidy eligible under this paragraph (c) that he or she does not need to apply for the subsidies under this subpart, and, at a minimum, is deemed eligible for a full subsidy as follows:

(i) For an individual deemed eligible between January 1 and June 30 of a calendar year, the individual is deemed eligible for a full subsidy for the remainder of the calendar year.

(ii) For an individual deemed eligible between July 1 and December 31 of a calendar year, the individual is deemed eligible for the remainder of the calendar year and the following calendar year.

* * * * *

Subpart V—Part D Marketing Requirements

102. Section 423.2260 is amended by revising paragraph (5)(vii) of the definition "Marketing materials" to read as follows:

§ 423.2260 Definitions concerning marketing materials.

* * * * *

Marketing materials. * * *

(5) * * *

(vii) Membership activities. Current enrollee communication materials include any informational materials that are—

(A) Targeted to current enrollees, and
(B) Customized or limited to a subset of enrollees or apply to a specific situation; or

(C) Cover claims processing or other operational issues.

* * * * *

103. Section 423.2262 is amended by—

A. Revising paragraph (a)(1)(i).

B. Adding new paragraphs (c) and (d) to read as follows:

§ 423.2262 Review and distribution of marketing materials.

* * * * *

(a) * * *

(1) * * *

(i) At least 45 days (or 10 days if using certain types of marketing materials that use, without modification, proposed model language and format, including standardized language and formatting, as specified by CMS) before the date of distribution, the Part D sponsor submits the material or form to CMS for review under the guidelines in § 423.2264 of this subpart; and

* * * * *

(c) Standardized model marketing materials. When specified by CMS, organizations must use standardized formats and language in model materials.

(d) Current enrollee communication materials. Current enrollee communication materials may be reviewed by CMS, which may upon review determine that such materials must be modified, or may not longer be used.

PART 480—ACQUISITION, PROTECTION, AND DISCLOSURE QUALITY IMPROVEMENT ORGANIZATION REVIEW INFORMATION

104. The authority citation for part 480 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

105. Section 480.140 is amended by adding a new paragraph (g) to read as follows.

§ 480.140 Disclosure of quality review study information.

* * * * *

(g) The QIO must disclose quality review study information with identifiers of MA plan beneficiaries, providers, practitioners, and services to CMS when CMS requests this information for the sole purpose of conducting activities related to MA organizations as described in § 422.153 of this chapter.

Authority: (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: August 13, 2009.

Charlene Frizzera,

*Acting Administrator, Centers for Medicare
& Medicaid Services.*

Approved: September 1, 2009.

Kathleen Sebelius,

Secretary.

[FR Doc. E9-24756 Filed 10-9-09; 4:15 pm]

BILLING CODE 4120-01-P



Federal Register

**Thursday,
October 22, 2009**

Part III

The President

**Notice of October 20, 2009—Continuation
of the National Emergency with Respect
to the Situation in or in Relation to the
Democratic Republic of the Congo**

Title 3—

Notice of October 20, 2009

The President

Continuation of the National Emergency with Respect to the Situation in or in Relation to the Democratic Republic of the Congo

On October 27, 2006, by Executive Order 13413, the President declared a national emergency with respect to the situation in or in relation to the Democratic Republic of the Congo and, pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701–1706), ordered related measures blocking the property of certain persons contributing to the conflict in that country. The President took this action to deal with the unusual and extraordinary threat to the foreign policy of the United States constituted by the situation in or in relation to the Democratic Republic of the Congo, which has been marked by widespread violence and atrocities that continue to threaten regional stability.

Because this situation continues to pose an unusual and extraordinary threat to the foreign policy of the United States, the national emergency declared on October 27, 2006, and the measures adopted on that date to deal with that emergency, must continue in effect beyond October 27, 2009. Therefore, in accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing for 1 year the national emergency declared in Executive Order 13413.

This notice shall be published in the *Federal Register* and transmitted to the Congress.



THE WHITE HOUSE,
October 20, 2009

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Thursday, October 22, 2009

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